DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID & MEDICAL ASSISTANCE

DELAWARE MEDICAL ASSISTANCE PROGRAM

PRACTITIONER PROVIDER SPECIFIC POLICY MANUAL

DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID & MEDICAL ASSISTANCE

Delaware Medical Assistance Program

Practitioner Provider Specific Policy Manual

Revision Table

Revision Date	Sections Revised	Description
1/1/02	Added a new Section 14.0	This policy is being added to define the service coverage for Prosthodontists.
7/1/02	All	Complete manual revision to reflect changes related to the MMIS and HIPAA compliance.
10/1/02	26.9, 26.18	1)As per the DUR Board we are deleting the prior authorization criteria for Filgrastim (26.9). 2) Adding prior authorization criteria for Paform (26.18).
7/1/02	Opening disclaimer	The change in language in the opening disclaimer is to make providers aware that there are required forms and procedures related to the Diamond State Partners.
1/17/03	26.12, 26.17, adding 26.19	Clarifying prior authorization criteria for requesting specific drugs
1/17/03	Adding 13.0, renumbering 14.0 through 28.0	A specific criteria section (13.0) is being added for FQHC providers. This addition will require the current sections 13.0-27.0 to be renumbered 14.0-28.0 in the text as well as the Table of Contents.
5/1/03	Adding 1.11.7.1 through 1.11.7.3	Medicaid may limit the quantity and duration of medications based on clinical appropriateness.
5/1/03	Adding 27.20 and 27.21	Adding prior authorization requirements for Selective Cox-2 Inhibitors and Proton Pump Inhibitors.
7/1/03	Adding 28.22	Adding prior authorization criteria for Enfuvirtide
7/1/02	Adding 28.23	Adding the Early Refill Request form, which has been used by providers since 7/1/02 but not accessible in the manual.
9/22/03	1.10, added 1.10.1, 1.10.1.1 and 1.10.1.2	This update is to clarify policy regarding how providers are to bill for injections.
9/23/03	28.16-28.18	Updating prior authorization criteria for Oxycodone and Morphine Sustained Release Product, Fentanyl Transdermal and Synagis.
10/14/03	1.15, 30.0	This update is to provide referring practitioners with information needed when requesting prior authorization for PET Scans.
10/1/02	1.7.1.4.3	DMAP limited home health aide services to 2 hours per day with additional hours requiring prior authorization. This policy applied to all ages. Although the change was made in the Home Health Provider Manual, it was not reflected in the Practitioner Manual.

Revision Date	Sections Revised	Description
1/1/04	Revised 1.11.6.2 and 28.21. Added 28.24	The Proton Pump Inhibitors prior authorization criterion is being revised and a new prior authorization criterion is being added for Nicotine Replacement Therapies. Language is being added to the manual that requires prior authorization for brand medications if a generic product is available.
1/13/04	Revised 29.8, 29.13, 29.15 and added 29.25 and 29.26	The prior authorization requirements for 5-HT3 Receptor Antagonists, Sevelamer and Cholinesterase Inhibitors are revised. Also, the same effective date, prior authorization requirements for DMARDS and Risperdal Consta are being added.
2/23/04	29.27 and 29.28	Prior authorization requirements for CNS Stimulants/atomoxetine and Lidocaine Topical Patch are being added.
3/22/04	1.0, 15.0, and 29.29	The DMAP is adding Clinical Nurse Specialist to the list of provider types that utilize this manual. A specific criteria for psychiatrist section is being added to clarify the codes this provider type must use when billing DMAP. Prior authorization requirements are being added for Levalbuterol HCI effective 4/1/04.
5/25/04	29.13 and 29.30	The prior authorization requirements for Sevelamer are being revised. Prior authorization requirements for Hemophilia Factor are being added.
06/10/04	29.31-23.33	Prior Authorization requirements are being added for Eplerenone, Tiotropium bromide inhalation powder and Cinacalcet.
06/10/04	29.3-29.7, 29.10-29.12, 29.14-29.17, 29.19-29.23, 29.26-29.27	Changed “Physician Name” to “Practitioner Name” and added Provider Number to several prior authorization requirements. Removed the requirement of the Physician Signature from several requirements. Added language to the following prior authorization requirements: 29.16, 29.17, 29. 20, 29.26 & 29.27.
06/24/04	29.15, 29.25, 29.31	Adding language to the prior authorization requirements for Cholinesterase Inhibitor, DMARDS and Eplerenone.
07/28/04	29.27	The prior authorization requirement for CNS Stimulants and Atomoxetine is being updated. In the Authorization section of the request, a Proposed Regimen field is being added.
8/24/04	18.0 and 19.0	Providers no longer use local codes. Therefore, references to these codes are removed from the manual.
9/29/04	29.34	Adding prior authorization requirements for Duloxetine HCI. The requirements are effective immediately.
10/1/04	29.20	In the General Requirement section of the Selective Cox-2 Inhibitors Prior Authorization Form a change is made in the second co-morbid condition.

Revision Date	Sections Revised	Description
10/5/04	29.18	Synagis for pre-term babies section of the prior authorization requirements is being updated by inserting the word “first” in front of RSV in three places.
11/3/04	29.7	This update changes the hematocrit level for chronic renal disease from 33% to 36% in the Restrictions section of the Epoetin-Alpha prior authorization requirements.
1/13/05	29.35, 29.36	Two new Prior Authorization forms are being added: (1) Anti-Depressants for the Pediatric Patient and (2) Epidermal Growth Factor Inhibitors – Gefitinib (Iressa®) and Erlotinib (Tarceva®)
1/13/05	29.13	The prior authorization requirements for Sevelamer are being revised; additionally, the section title is changed to “Phosphorous Binders”.
1/18/05	29.37, 29.38, 29.39	Three new Prior Authorization forms/criteria are being added: (1) Teriparatide 250 mcg/ml solution (Forteo SubQ®); (2) Hydromorphone Hydrochloride Extended Release (Palladone®); and (3) Buprenorphine and Buprenorphine/Naloxone tablets (Subutex® and Suboxone®)
1/26/05	29.40	One new Prior Authorization form/criteria is being added: Dronabinol.
1/26/05	29.41	One new Prior Authorization form/criteria is being added: Anti-Depressants for the Adolescent Patient Between the Ages of 6-18 Years.
1/26/05	29.35	A back page is added to the prior authorization form titled “Anti-Depressants for the Pediatric Patient”: Anti-Depressant Use in Children and Adolescents.
1/26/05	29.42	One new Prior Authorization form/criteria is being added: Request for Quantity Limitation Override.
1/26/05	29.43	One new Prior Authorization form/criteria is being added: Tegaserod Maleate (Zelnorm®)
2/04/05	29.10, 29.34, 29.44	The prior authorization forms for Oral Antifungal and Duloxetine HCI have been removed. A prior authorization form for Step Therapy has been added.
2/11/05	29.13	The general requirements for the prior authorization form, Phosphorous Binders, are being revised to add the following information to #4: >150pg/mL or bi-PTH>80pg/mL and to correct the spelling of (Pho-Lo) under “Authorization”; it should read (Phos-Lo).
3/9/05	29.13	The general requirements for the prior authorization form, Phosphorous Binders, are being revised to change the Lanthanum Carbonate dosing from 1500mg daily to 3000mg daily.
3/31/05	29.45	Added Preferred Drug List (PDL) Override Form effective April 1, 2005.
3/31/05	ALL	The DMAP website address has been added to the header of all pages.

Revision Date	Sections Revised	Description
3/31/05	29.21	Effective April 1, 2005, Lansoprazole no longer requires Prior Authorization for daily or twice daily dosing.
3/31/05	29.43	Added a chart to the General Requirements section of the PA form for Tegaserod Maleate (Zelnorm®).
3/31/05	29.25	The prior authorization form for “Disease-Modifying Antirheumatic Drugs (DMARDS)” has been removed.
4/6/05	29.12, 29.14, 29.20, 29.27, 29.28	Updated prior authorization criteria for Modafinil (Provigil), Duplicate Therapy, Selective COX-2 Inhibitors (Celecoxib, Valdecoxib), CNS Stimulants and Atomoxetine, and Lidocaine Topical Patch (Lidoderm 5%)
4/11/05	29.23	Changed the Pharmacy Team contact number to read 800-999-3371.
5/27/05	29.38, 29.46, 29.47, 29.31	1) Updated prior authorization criteria for Hydromorphone Hydrochloride Extended Release (Palladone®) 2) Added prior authorization criteria for Eszopiclone (Lunesta®) 3) Added prior authorization criteria for Alprazolam Alternative Dosage Forms (Niravam®, Xanax®) 4) Deleted prior authorization form/criteria for Eplerenone (Inspra®)
8/8/05	Replaced 6.2 – 6.5.1.9 with 6.2-6.3.3.7.2	Revised definition of sick eye visit. Updated prior authorization criteria.
8/22/05	29.6, 29.11, 29.12, 29.13, 29.15, 29.20, 29.33, 29.38, 29.46, 29.48, 29.49, All PA Forms	Prior authorization criteria was updated to coincide with recommendations by the Drug Utilization Review Board. The DMAP website has been added to the bottom of all prior authorization forms.
10/14/05	29.20	Ankylosing Spondylitis has been added as a covered condition.
10/14/05	29.7, 29.13, 29.16, 29.17	The DMAP preferred product has been added to the top of each form.
10/14/05	29.50	The prior authorization form for Sildenafil has been added.
11/04/05	1.0	Added bullet for Independent Certified Registered Nurse Anesthetists.
11/04/05	1.5, Added:1.5.1, 1.5.1.1, 1.5.1.2, 1.5.1.3 and 1.5.1.4	Renamed section and added subsections to include services covered as part of other services.
11/04/05	1.13.1 – 1.13.2.1	Reorganized to correct formatting.
11/04/05	5.0	Renamed section.
11/04/05	5.1-5.6	Replaced “anesthesiologists” and “physician” with “anesthesiology provider”.

Revision Date	Sections Revised	Description
11/04/05	Added new section 5.7, 5.7.1, 5.7.1.1 and 5.7.2	Added sections to include policy for Independent Certified Registered Nurse Anesthetists.
11/04/05	30.1 and added 30.2	Named and numbered the periodicity schedule. Renumbered the section worded Routine Gynecological Evaluation.
11/21/05	1.8.2.3	Removed reference to “Map 25” and removed reference to Appendix A.
11/21/05	13.0	FQHC policy removed from Practitioner Provider Specific Policy Manual. FQHC Provider Specific Policy Manual created. Content Remained unchanged.
11/21/05	16.0	Removed Map 25 Comprehensive Medical Report form. This form is provided by DMMA at the time of application. Titled section Reserved.
11/23/05	29.51, 29.52, 29.53	Authorization forms have been added for Rozerem, Ambien CR and Symlin.
11/23/05	29.22	Removed the authorization form for Fuzeon.
11/23/05	29.27	The authorization form for CNS Stimulants and Atomoxetine has been updated to clarify the general requirements.
12/19/05	29.42	Albuterol has been added to the Request for Quantity Limitation Override form.
3/21/06	1.11.2.7	Added policy regarding coverage of drugs to promote weight gain.
3/21/06	29.40	Replaced prior authorization form for Dronabinol with a prior authorization form for weight gain promoting agents.
3/21/06	29.11.1	The MedWatch form has been moved from 29.12.1 to 29.11.1
4/11/06	29.46, 29.51, 29.52	Removed the prior authorization forms for Eszopiclone, Ramelteon and Zolpidem.
4/11/06	29.42	Removed the Pharmacy Limitation for Sedatives/Hypnotics.
5/15/06	29.16, 29.17	Avinza has been added as a preferred long acting opioid.
11/8/06	29.2, 29.8, 29.12, 29.13, 29.15, 29.20, 29.21, 29.24, 29.26, 29.27, 29.29, 29.32, 29.44, and 29.48	Added clarification to existing prior authorization forms. Authorization form for Step Therapy (29.44) was removed and reserved for future use.
11/8/06	29.54	Authorization form for Methylphenidate (DAYTRANA™) was added.
11/28/06	29.19, 29.55 and 29.56	Section 29.19 was updated. Authorization forms have been added for Insulin Human (Inhalation) Exubera® and (Sitagliptin phosphate) Januvia™
4/3/07	29.57, 29.58 and 29.59	Authorization forms for Methadone (Methadose®), Naltrexone Hydrochloride (Vivitrol™), and Pimecrolimus (Elidel®) and Tacrolimus (Protopic®) have been added.
5/31/07	20.0	Glucose monitors have been added to the inclusion list.

Revision Date	Sections Revised	Description
5/31/07	29.24, 29.48, 29.56, 29.60 and 29.61	Sections 29.24, 29.48 and 29.56 have been updated. Authorization forms have been added for Lubiprostone (Amitiza®) and Hepatitis C Agents.
6/25/07	29.16 and 29.17	The criteria forms for Oxycodone and Morphine Sustained Release Products and Fentanyl Transdermal have been updated.
10/5/07	29.8, 29.15, 29.20 and 29.58	The criteria forms for 5-HT3 Receptor Antagonists, Cholinesterase Inhibitors, Selective COX-2 Inhibitors and Naltrexone Hydrochloride have been updated.
10/5/07	1.11.1.5	Added newly mandated tamper resistant prescription pad policy.
12/21/07	10.1	A new procedure for billing allergy injections is effective for dates of service January 1, 2008 and after.
4/9/08	29.62 and 29.63	Authorization forms have been added for Maraviorac (Selzentry®) and Pregabalin (Lyrica®)
4/9/08	29.8, 29.16, 29.17, 29.27, 29.29, and 29.42	The criteria forms for 5-HT3 Receptor Antagonists, Oxycodone, Fentanyl Transdermal, CNS Stimulants, Levalbuterol HCl (Xopenex®), and Quantity Limit Overrides have been updated.
7/22/08	1.11 and 1.2	DMMA coverage for FDA approved indications and clarification of the reporting requirement of the National Drug Code (NDC).
8/14/08	1.11	Update to correct the wording associated with the listed publication examples.
8/14/08	20.0	Effective 9/5/08 cough and cold-oral, and diabetes supplies will be added to the PDL.
8/15/08	1.9	Update to the information on supplies used in an office visit or office surgical procedure.
9/18/08	Manual Heading, 29.64 and 29.65	Removed obsolete numbering. Authorization forms have been added for Leukotriene Receptor Antagonists and Inhaled Glucocorticoid/Beta-Agonist Combination.
10/7/08	30.0 Appendix O	Added wording to the Periodicity schedule regarding number of visits for early childhood years.
1/8/09	1.11.8.3 and 29.0	Updated the location to access specific criteria for prior authorization.
4/22/09	1.2	Update to define our requirement that the practitioner(s) signature is on all medical records.
7/13/09	30.0 Appendix O	Corrected the wording to the Periodicity schedule regarding the number of visits for early childhood years, between the ages of 2 and 3.
9/21/09	1.11.3	Updated to replace the requirement for a DEA number with the NPI.
10/30/09	1.14 and 29.0 – Appendix N	Bariatric surgery was added to the list of exclusions in Section 1.14. Appendix N was updated to “Reserved for Future Use”.
1/19/10	1.4.1	Update to reflect that for dates of service January 1, 2010 and after, the Delaware Medical Assistance Program (DMAP) will no longer cover inpatient and outpatient consultation codes.

Revision Date	Sections Revised	Description
7/12/10	1.14.8 through 1.14.8.9.9	Addition of transplants subsection
7/12/10	1.14.9 through 1.14.9.3	Addition of bariatric surgery subsection
7/12/10	1.15 through 1.15.1.2	Removed the subsection titled Non-Invasive Therapy
7/12/10	7.3 through 7.3.2.4	Addition of section regarding prior authorization for PET scans and computed tomographic colonography
7/12/10	1.15 through 1.15.2.2	Addition of section regarding Sleep Testing
3/8/11	12.1	Removal of obsolete language regarding the reimbursement of hospital based emergency room physicians who are independent of the hospital.
3/16/12	5.5	Update to the definition of “Time Units”.
4/26/12	1.11.8.3	Removed obsolete wording.
7/1/14	1.9.1	Added “Oral Abortive Agents”
7/1/14	1.9.2	Added clarification for treatment coverage at a “Medication Assisted Outpatient Treatment Program (MAOTP)”
9/1/14	1.11.7.1 – 1.11.7.4	Added language to clarify limitations on prescriptions, revised section numbering.
10/1/14	Table of Contents	Added specific criteria for chiropractic providers in section 13. Added “Appendix Q.”
10/1/14	1.0	Added “Chiropractor” to list of practitioners.
10/1/14	13.0	Added specific criteria to define the service coverage for Chiropractic Providers and effective date of 10/1/2014.
10/1/14	32.0	Added “Appendix Q” as related to chiropractic billing codes.
11/1/14	1.14.8	Provided additional coverage descriptions and clarification of transplant services. Updated section numbering.
2/1/2016	Table of Contents	Added Prior Authorization
2/1/2016	15.2	Added Prior Authorization for Transcranial Magnetic Stimulation Behavioral Health Services
02/01/2016	4.4.8	Added language and guidance regarding Oral Health Screening and Treatment.
02/01/2016	9.0	Billing procedures
02/01/2016	14.0	Updated prior authorization criteria for Prosthodontists
4/01/2016	4.0	Added Fluoride Varnish Policy.
07/06/2016	General Information	DSP Language removed.
7/22/2016	Appendix E	Updated Category description from Lice Control Preparations to Topical Antiparasitics. Added additional Inclusions.
12/1/2016	16.0	Manual updated to include Telemedicine Policy.
02/01/2017	9.1	Update to reflect the policy regarding the removal of bony impacted wisdom teeth effective 7/1/2014.

Revision Date	Sections Revised	Description
04/01/2017	13.0	Section updated in compliance with the Delaware Medicaid Enterprise System (DMES) and updates to the State Plan.
04/01/2017	13.2.2	Updated 'twelve month period' to 'calendar year'.
7/1/2017	13.0	Section updated in compliance with the Delaware State Plan.
3/15/2018	18.0	Added the Treatment of Gender Dysphoria Disorder policy in compliance with the Delaware State Plan
6/15/2018	4.1	Updated section to add fluoride varnish as an MCO covered benefit effective January 1, 2016.
6/22/2018	13.1.3	Added chiropractic services as a MCO covered benefit effective January 1, 2018.
10/1/2018	13.2	Updates added to include 'rolling calendar year'.
10/1/2018	32	Added billing codes 72081, 72082, 72083, and 72084. Removed billing codes 72010 and 72090.
01/01/2019	1	Added Physician Assistants to the referenced provider types.
02/01/2019	4.4	Updated EPSDT Services and Guidelines to align with the American Academy of Pediatrics / Bright Futures recommendations for preventive pediatric health care.
02/01/2019	13.2.2	Chiropractic Services policy updated to remove service limitations in compliance with 42 CFR 440.60(b).
02/01/2019	13.2.3	Added Necessity of Treatment policy for Chiropractic Services.
02/01/2019	30.1	Updated EPSDT Periodicity Schedule to align with the American Academy of Pediatrics / Bright Futures recommendations for preventive pediatric health care.
02/21/2020	All	In compliance with the registered trademark of the American Medical Association added the ® symbol to each instance of CPT®.
05/20/2021	4.4	Added new section regarding nutritional counseling, education and intensive behavioral therapy to align with the State Plan and the United States Preventive Services Task Force (USPSTF) recommendations for Obesity Treatment and Intervention.
11/19/2021	9.1	Section updated to reflect coverage under the Adult Dental Program.
02/21/2022	1.11.8.2	Added language to specify requirements and limitations for 72-hour emergency prescription medication.
09/23/2022	1.11.2.6	Section updated in alignment with the State Plan to cover drugs indicated for the treatment of obesity to address weight loss with co-morbid conditions with prior authorization.
09/23/2022	13.2	Section revised in compliance with the State Plan.

Revision Date	Sections Revised	Description
09/23/2022	32.0	Removed Appendix Q – Chiropractic Billing Codes.
10/28/2022	2.3	Section updated to align with DMAP medical necessity guidelines.
10/28/2022	22 Appendix G	Awareness Form updated to align with DMAP medical necessity guidelines.
06/28/2023	27.4, 27.5, 27.6 and 27.7	Sections updated in alignment with references to the Current Procedural Terminology (CPT®) Manual for correct codes as published by American Medical Association (AMA).
07/01/2023	All	Updated sections to reflect the removal of paper claims information in compliance with DMES and electronic claims filing requirements.
07/01/2023	All	Universal updates to align Delaware Medicaid Enterprise System (DMES) and Delaware Medical Assistance Portal administrative language.
01/01/2024	16.0	Added new section regarding Telehealth Services policies and procedures to align with the State Plan.
01/12/2024	1.0	Updated section in compliance with current provider descriptions and policy requirements.
01/12/2024	17.0	Added specific criteria for annual behavioral health well check in compliance with 24 Del Admin. Code Title 31 Chapter 5 §531.
12/20/2024	1.0	Updated section in compliance with current provider descriptions and policy requirements for Certified Registered Nurse Anesthetist (CRNA) providers.
12/20/2024	2.6	Updated section to align with Delaware Medical Assistance Portal administrative language.

DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID & MEDICAL ASSISTANCE

Delaware Medical Assistance Program

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Practitioner Provider Specific Policy

Health care services are provided to the majority of Medicaid members through the Diamond State Health Plan (DSHP), Medicaid's managed care program. Practitioner services are included in the managed care benefits package. Refer to the Managed Care section of the General Policy for information related to the DSHP. All Medicaid members who are enrolled with a managed care organization (MCO) must receive practitioner services through the MCO.

This manual reflects the policies as they relate to Medicaid members who are exempt from managed care coverage or who may require practitioner orders to receive services outside the MCO package (see list of those exempt from managed care coverage in the Managed Care section of the General Policy).

This manual is to be used in conjunction with the General Policy Manual and the General Billing Manual which are located on the Delaware Medical Assistance Portal for providers.

1.0 General Information

This manual contains policies and procedures to be utilized by practitioners who shall include the following provider types:

- Physicians: Doctor of Medicine (M.D.) and Doctor of Osteopathy Medicine (D.O.)
- Midwives
- Podiatrists
- Nurse Practitioners
- Licensed Behavioral Health Practitioners/Clinicians
- Optometrists
- Chiropractors
- Physician Assistants
- Clinical Nurse Specialists
- Certified Registered Nurse Anesthetists (CRNA)
    - A CRNA who practices under the supervision of an Anesthesiology Physician or Dentist Anesthesiologist may only enroll under the taxonomy 367500000X.
    - A CRNA who does not practice under the supervision of an Anesthesiology Physician or Dentist Anesthesiologist may only enroll under the taxonomy 367H00000X.
- Group practices may enroll in the Delaware Medical Assistance Program (DMAP) and use their provider identification number to bill. However, individual practitioners who are members of the group must also have individual contracts and individual DMAP provider numbers. The practitioner's number must be used to identify the provider performing the service on the claim form submitted by the enrolled group.

1.1 Practitioner Services

1.1.1 Practitioner services, for the purpose of this manual, are those services furnished in the office, the member's home, a hospital, a skilled or intermediate nursing facility, clinic or elsewhere, and are defined as services provided:

1.1.1.1 Within the scope of practice as defined by state law; and

1.1.1.2 By or under the personal supervision of an individual licensed under state law to practice medicine.

1.1.2 A practitioner is permitted to bill the DMAP for covered services provided by:

1.1.2.1 Self

1.1.2.2 Certified and registered physician's assistant, licensed registered nurse, licensed practical nurse, audiologist, physical or speech therapist, medical technologist or laboratory technician provided that the individual performing the service is in an enrolled practitioner's or an enrolled group's employ. An individual will be considered to be an employee if the individual is under the control of the employer about when, where, and how to work and if the employer is obligated to pay the Social Security taxes for the individual

1.1.2.3 An out-of-state practitioner contracted to provide coverage on a Locum Tenens basis [reference Delaware Code, 24 Del. C. Section 1725 (a) (1)] when the enrolled practitioner is temporarily ill or absent from the state. The enrolled practitioner or group must keep documentation of the temporary license issued by the enrolled practitioner's state.

1.1.3 A practitioner is prohibited from billing the DMAP for covered services provided by:

1.1.3.1 Any other practitioner except as noted above (this rule applies to all practitioners including partners and employees

EXAMPLE: Dr. A is on call for Dr. B and provides medical care to Dr. B's patient. Dr. A must bill, or if in a group practice, be identified as the performing provider on the claim for the services provided to Dr. B's patient. Dr. B may NOT bill for these services.

1.1.3.2 A resident or intern employed by a hospital.

1.2 Practitioner Documentation Requirements

1.2.1 Practitioners who bill the DMAP for services provided to eligible Medicaid members are required to verify that they actually rendered the service which is being billed. The following are the documentation requirements to verify the identity of the performing provider.

1.2.1.1 A practitioner in a solo practice is required to sign or initial medical records. DMAP requires a legible identifier for any services ordered or provided.

1.2.1.2 A performing provider in a group practice is required to sign or initial medical records. DMAP requires a legible identifier for any services ordered or provided.

1.2.1.3 Practitioners enrolled with the DMAP must countersign the services performed by the interns or residents they oversee or supervise.

1.2.2 Providers are required to submit the corresponding 11 digit National Drug Code (NDC) of the actual product administered when billing for a HCPCS procedure code that is for a pharmaceutical. The medical chart should include the same notation documenting that the specific product was administered.

1.3 Practitioner Programmatic Responsibility

1.3.1 Practitioners should be aware of their responsibility when signing or completing an order or prescription for any service covered by the DMAP on behalf of a Medicaid

member. The decision to allow or deny some necessary services is based on the practitioner's assessment of the patient's condition.

1.3.2 If the practitioner misrepresents or falsifies the essential information upon which payment of federal/state funds is based, the practitioner may, upon conviction, be subject to a fine and imprisonment under federal/state laws. In order to avoid potential prosecution, the practitioner must clearly and accurately represent his/her clinical assessment of the patient's condition and the functional status the practitioner is using in prescribing the necessary services.

1.3.3 Practitioners have the ethical and programmatic responsibility to direct members to the most appropriate, medically necessary, and cost-efficient care possible.

1.3.4 "Practitioner-induced (outpatient) emergency room abuse" causes the cost of medical care to increase and adds an undue burden on everyone supporting and associated with the DMAP. It is important that practitioners not refer patients to the emergency room(s) for routine matters. Practitioners must consider referrals to the outpatient emergency room(s) only when a potential life-threatening situation exists.

1.4 Major Differences from Level I HCPCS

The major differences from the Level I HCPCS (Health Care Administration Common Procedure Coding System) procedure codes are listed in the following section. However, since this list will not be all-inclusive, providers are urged to carefully read the provider newsletter that is mailed periodically. Additional information concerning changes, additions, and/or alterations to HCPCS procedure codes will be published in the newsletter.

1.4.1 Consultation Codes

Effective 01/01/2010 the DMAP will no longer cover inpatient or outpatient consultations. In lieu of billing a consultation code, providers should bill the E/M code appropriate for the service provided.

1.5 Services Covered as Part of Other Services

1.5.1 The following services are considered included in the provision of another service (such as a visit, therapy or imaging service) and are not separately reimbursed:

1.5.1.1 Manipulation of the chest wall such as cupping, percussing, and vibration.

1.5.1.2 Provision of radiopharmaceutical diagnostic or therapeutic imaging agents.

1.5.1.3 Removal of devitalized tissue from wounds using non-selective debridement without anesthesia.

1.5.1.4 Removal of impacted cerumen.

1.6 Observation Services

1.6.1 The DMAP covers outpatient observation services in acute care settings. Outpatient observation services must be physician-ordered services, and be reasonable and necessary to evaluate a patient's condition or determine the medical necessity of an inpatient admission. Observation services are those hospital services furnished on a hospital's premises and are not required to be provided in the actual outpatient area or on a designated unit. The observation services can be provided in any area of the facility with periodic monitoring by the hospital staff.

1.6.2 Observation services are implemented for an anticipated short length of stay. Observation services must not exceed 48 continuous hours. The physician must indicate in the order that the patient should be moved to an observation bed or service. The patient is still considered an outpatient. The provider should clearly document the time at which the patient is admitted as an outpatient in observation status.

1.6.3 The following types of services are not covered as observation services:

1.6.3.1 Services that are not reasonable and necessary for the diagnosis of the patient

1.6.3.2 Services provided for the convenience of the patient or provider

1.6.3.3 Services that are not physician ordered.

1.6.4 Providers are not expected to substitute outpatient observation service for medically appropriate inpatient admissions.

1.6.5 For patients who are admitted as an inpatient from observation services, all outpatient services rendered by the admitting facility prior to the admission are included in the inpatient discharge payment and may not be billed separately as an outpatient claim.

1.7 Home Health Services

1.7.1 Practitioners may prescribe home health services when all the following general criteria are met:

1.7.1.1 The member must be eligible for Medicaid on the dates home health services are delivered. The home health agency (HHA) should be alert to any member restrictions by accessing one of the EVS options. Instructions to accessing EVS is described in the EVS section of this manual. Home health services are included as part of the MCO benefits package. Members who are enrolled with an MCO must receive home health services from their MCO. The HHA may not bill the DMAP for these services.

1.7.1.2 The home health service must be provided at the member's place of residence. The place of residence is a person's primary permanent dwelling. Home health services may be provided at other locations when the member is required to be away from their primary permanent dwelling during some part of the day. A person's place of residence, for the purpose of home health services does not include a hospital or a nursing facility.

1.7.1.3 The attending practitioner must establish a written plan of care that documents medical necessity and contains the following components:

1.7.1.3.1 Diagnoses, prognosis, symptoms, complaints and complications that justify that the residence is the most appropriate place to deliver the services

1.7.1.3.2 A description of the mental and physical functional level, rehabilitation potential, activities permitted and nutritional requirements of the individual who requires home health services

1.7.1.3.3 Orders for medications, treatments, special therapies, supplies and durable medical equipment including the specific procedures and modalities to be used

1.7.1.3.4 Orders for skilled nursing and rehabilitation visits that clearly specify amount, frequency and duration of the required home health services. Orders for home health aide (with or without skilled service) should include hours per visit in addition to the above requirements

1.7.1.3.5 Safety measures to protect against injury

1.7.1.3.6 Prior authorization must be obtained by the HHA in situations where there are multiple members in the same household requiring similar home health services and/or multiple HHAs in the same household rendering similar home health services. Medical necessity in these situations will be those services required to identify or treat any illnesses or injuries collectively for the individuals requiring home health services. The Medical Review Team will evaluate the service requirements on an individual basis

1.7.1.3.7 Review of the plan of care by the prescribing practitioner as often as the severity of the patient's condition requires, but at least every sixty days. The HHA should alert the practitioner, through the summary report, to any changes that suggest a need to alter the plan of care.

1.7.1.4 The need for home health care must fall into one of the following four categories and meet the technical criteria for that category.

1.7.1.4.1 Category 1: Skilled Nursing Services - The member of skilled nursing services needs part-time or intermittent skilled nursing service.

1.7.1.4.2 Category 2: Skilled Rehabilitation Services - The member of skilled rehabilitation services needs part-time or intermittent skilled rehabilitation services.

1.7.1.4.3 Category 3: Home Health Aide Services - The member of home health services in this category needs part-time or intermittent services by a home health aide.

Home health aide services are limited to a maximum of two hours per day. The number of days/weeks that the service is medically necessary must be prescribed. If a condition exists that requires more than the maximum, prior authorization must be obtained by the HHA for additional units.

The member must have a medical diagnosis and need medically oriented services.

1.7.1.5 The DMAP, under Home Health Services, does not cover respite or child/adult day care activities.

1.8 Practitioner Responsibility for Member in Need of Skilled or Intermediate Nursing Facility Care

The DMAP reimburses long-term care facilities for services rendered to members who are in need of:

1.8.1 Skilled Nursing Care

1.8.1.1 Skilled nursing care is provided to those people who need, on a daily basis (24 hr./day, 7 days/wk.), skilled nursing services or skilled rehabilitation services, which as a practical matter can be provided only in a skilled nursing facility on an inpatient basis.

1.8.1.2 Daily skilled care must be provided directly by or requiring the supervision of technical or professional personnel, i.e., registered nurse, licensed practical (vocational) nurse, physical therapist, occupational therapist, speech pathologist, audiologist.

1.8.2 Intermediate Care

1.8.2.1 Intermediate care is provided to those people who require nursing services, whether it be supervision, observation, assistance, and/or intervention, but do not need these services on a “24 hr./day, 7 days/wk.” basis.

1.8.2.2 The DMAP does not reimburse for members who need rest/residential (domiciliary) care.

1.8.2.3 Before a member is approved for any long-term care (institutional or home and community based) program, the attending practitioner must complete a Comprehensive Medical Report. The member is then evaluated by the Medicaid agency or its designee for assignment of level of care and assessment of active treatment need for mental retardation, developmental disability, and/or mental illness. The member and/or his representative have the right to appeal decisions regarding these assignments.

1.8.2.4 Once admitted to a long term care facility, the attending practitioner is obligated to perform certain evaluations and documentation as established by federal and state regulations pertaining to nursing home care. These include, but are not limited to:

Certification and recertification of level of care (in ICF/MR and ICF/IMD facilities only).

Admission and continuing written orders for patient care:

- Not to exceed every thirty days - skilled care.
- Not to exceed every sixty days - intermediate care.

Physical examination within forty-eight hours after admission and annually (not to exceed three hundred and sixty-five days thereafter).

Regular practitioner visits and progress notes:

- Not to exceed every thirty days - skilled care.
- Not to exceed every sixty days - intermediate care.

1.9 Coverage of Supplies Used in Office Visit or During Office Surgical Procedure

Supplies, other than injectable substances and oral abortive agents, used by a practitioner in the course of an office visit, home visit, or office surgical procedure are included in the reimbursement for the office visit, home visit, or surgical procedure. Supplies cannot be billed as a separate item.

1.9.1 Oral Abortive Agents – Misoprostol

1.9.2 Medications administered for the treatment of opioid dependence are covered separately through a certified Medication Assisted Outpatient Treatment Program (MAOTP). See Sections 3.1.1.3 and 7.0 of the Clinic Provider Specific Manual for additional information.

1.10 Injections

1.10.1 When billing for an injection the following procedure should be followed:

1.10.1.1 If the injectable substance is provided by the practitioner it may be billed using the appropriate procedure code.

1.10.1.2 The doctor's/nurse's time and any supplies are billed using a procedure code which appropriately describes the level of office visit provided.

1.11 Pharmacy Services

1.11.1 Covered Services

1.11.1.1 Outpatient prescriptions

1.11.1.2 All legend (i.e., prescription only) drugs from drug labelers participating in the Federal Medicaid Drug Rebate Program.

1.11.1.3 Medical devices which require a prescription such as diabetic supplies, syringes, and diaphragms regardless of labeler.

1.11.1.4 Certain over-the-counter (OTC) products for non-institutionalized members. Practitioners are encouraged to utilize OTC products whenever appropriate. A list of the therapeutic classes are included for your reference. See Appendix E for a copy of this document. The labeler of the OTC product must also be participating in the Drug Rebate Program.

1.11.1.5 Providers are responsible for using DMAP approved tamper resistant prescription pads or electronic prescription methods for all outpatient drugs unless you are prescribing for institutional or group settings that validate all requested medication and the dispensed quantities.

1.11.1.6 DMMA will reimburse for prescription medications which: 1) are prescribed for an FDA approved indication(s), 2) are prescribed for indications, dosages, and formulations that are part of national standards developed, or 3) are prescribed for indications, dosages, and formulations that have been shown to demonstrate both efficacy and safety in a minimum of two peer reviewed journals. Any other prescriptions are considered experimental and therefore not covered unless specific written authorization has been given by DMMA for an individual member based on a demonstration of medical necessity. In these situations Providers should complete

and submit the appropriate authorization form in Appendix N-Criteria for Drug Prior Authorization.

1.11.2 Non-Covered Services

1.11.2.1 DESI Drugs

DESI drugs are products and known related drug products that lack substantial evidence of effectiveness. The DMAP does not reimburse DESI drugs classified by CMS as a “5” or “6”. Members must be advised prior to the delivery of the prescription that the DMAP does not cover the item. The member may either pay for the drug or be advised to contact his/her physician who may write a prescription for a Medicaid-covered product (the pharmacist may also elect to advise the physician on behalf of the member).

Providers who do not have a DESI drug list may obtain one by contacting the DMAP Fiscal Agent, Provider Relations. Contact information for the Fiscal Agent is located in the Index, Section 20.0, of the General Policy Manual.

1.11.2.2 Drugs Used For Cosmetic Purposes

Drugs used for cosmetic purposes are not routinely covered by the DMAP. The DMAP defines the treatment of acne, hair growth retardation and hair growth stimulation in adults as cosmetic. Adults are defined as anyone 21 years of age or older. Medications for adults suffering from these conditions are not covered. In extraordinary cases where medical necessity is well documented, the case may be reviewed for reconsideration.

1.11.2.3 Fertility Drugs

The DMAP will not routinely reimburse for drugs that are prescribed to stimulate fertility.

1.11.2.4 Medical Necessity/Investigational Drugs

The DMAP will only cover drugs that have a FDA approved indication. The indication must have medical necessity. Drugs that have investigational status only are not routinely covered.

The DMAP does not routinely cover injectable or oral medications that are used to correct sexual dysfunction.

1.11.2.5 Compound Prescriptions

Compound prescriptions must include at least one medication that on its own, would be a covered entity. The combination of several non-covered products will not allow for coverage.

1.11.2.6 Drugs for Obesity

Drugs indicated for the treatment of obesity to address weight loss with co-morbid conditions are covered by DMAP with prior authorization. Medications to reduce weight for the sole purpose of cosmetic reasons are not a covered benefit.

1.11.2.7 Drugs to Promote Weight Gain

1.11.2.7.1 Drugs indicated for promoting weight gain are not routinely covered by the DMAP. Drugs used for promoting weight gain may be covered for the treatment of AIDS wasting or cachexia.

1.11.3 NPI Number

The prescribing practitioner should provide the pharmaceutical provider with their federal National Provider Identifier (NPI). This number is used by the DMAP to process pharmacy claims.

1.11.4 Reserved

1.11.5 Drug Rebate Programs

1.11.5.1 For the Medicaid (Title XIX) population including the Diamond State Health Plan (DSHP) managed care eligibles, prescription drugs are restricted to medically necessary products manufactured by pharmaceutical companies that agree to provide manufacturer rebates under the CMS rebate agreement.

1.11.5.2 For the Delaware Health Children Program (DHCP), the Chronic Renal Care Program, the State Program for Non-Qualified, non-Citizens, and the Delaware Prescription Assistance Program, prescription drugs are restricted to medically necessary products manufactured by pharmaceutical companies that agree to participate in the State Rebate Program.

1.11.6 Delaware Maximum Allowable Cost (DMAC)/Federal Upper Limit (FUL) Drugs

1.11.6.1 The DMAP has a DMAC program and utilizes the federally defined Federal Upper Limit (FUL) drugs and prices. The DMAC program is an extension of FUL. DMAC/FUL drugs are products for which the DMAP has financial limitations. The provider is free to dispense the defined product(s) as he/she wishes (within the requirements of the State laws pertaining to pharmacies), but Medicaid will not exceed the pricing limit. Essentially, a state Medicaid Program is prohibited by federal regulation from reimbursing providers amounts in excess of these financial limits.

1.11.6.2 Brand medications will require prior authorization if a generic product is available. Refer to Appendix N for specific criteria for drug prior authorization. For these medications a Food and Drug Administration Med-Watch form must be submitted for review.

1.11.7 Prescription Quantity Limitation

Prescriptions are limited to a quantity not to exceed the greater of 100 dosing units or a 34-day supply.

1.11.7.1 Physicians must not generate two prescriptions for the same medication, for the same member, on the same date of service.

1.11.7.2 Prescriptions are limited to a quantity not to exceed the greater of 100 dosing units or a 34-day supply

1.11.7.3 The DMAP may choose to limit the quantity of any medications per 30-day period.

1.11.7.4 The DMAP may limit the duration of time that a member may receive medication during a 12-month period or may establish a lifetime limit for particular classes of drugs or specific products.

1.11.8 Prior Authorization Requirements for Medications

1.11.8.1 Medications may be prior authorized if one of the following issues is present:

1.11.8.1.1 Medical necessity is lacking or is not clearly evident

1.11.8.1.2 Potential for diversions, misuse and abuse

1.11.8.1.3 High cost of care relative to similar therapies

1.11.8.1.4 Experimental use opportunity

1.11.8.1.5 Drug classes where the potential for not keeping within the policy guidelines of the DMAP are identified.

1.11.8.2 The pharmacy provider or the practitioner can initiate the request for prior authorization. Requests will be evaluated within one business day by Medicaid's pharmacy consultant or medical director. If a request is submitted when prior authorization is not available and a delay would endanger the health or welfare of the member, one 72-hour emergency supply can be dispensed. An emergency supply can only be dispensed once per drug per member during a 60-calendar day period.

1.11.8.3 The Drug Utilization Review Board will make decisions regarding the medications that will require prior authorization and the criteria to be used. Prior authorization will be based on duration of therapy, quantity, or a combination of both depending on the medication requested. Refer to the DMAP Web site at https://medicaid.dhss.delaware.gov/ for specific criteria for prior authorization.

1.12 Practitioner Laboratories

1.12.1 General Information

1.12.1.1 The DMAP reimburses enrolled providers for properly ordered, medically necessary, non-experimental, non-investigational, Clinical Laboratory Improvement Amendments (CLIA) certified laboratory services when properly performed, documented, and billed.

1.12.1.2 All tests performed by a practitioner in his/her laboratory must be documented by a written order from the ordering practitioner. The signing of the practitioner's name by another individual or the use of facsimiles are not acceptable. Any telephone order for laboratory testing must be supported by a signed order from the practitioner.

1.12.1.3 As a result of Public Law 98-369, the DMAP prohibits practitioners from billing for clinical diagnostic laboratory tests that are not personally performed or supervised by the practitioner start-to-finish in his/her office. The following policies apply:

1.12.1.3.1 Practitioners may only bill the program for those laboratory procedures that they personally perform or supervise start-to-finish in their office.

1.12.1.3.2 Laboratory procedures that the practitioner refers to an outside laboratory must be billed by the laboratory.

1.12.1.3.3 Interpretation of laboratory results or the taking of blood or other specimens is considered part of the visit and may not be charged as a separate procedure by the practitioner.

1.12.2 CLIA

The Clinical Laboratory Improvement Amendments of 1988 were enacted by Congress to improve the quality and reliability of clinical laboratory testing. CLIA applies to any provider who performs any laboratory test used for health purposes, no matter how simple or routine.

1.12.3 CLIA Certificate of Waiver Tests

1.12.3.1 A practitioner who holds a CLIA Certificate of Waiver may bill the DMAP for clinical diagnostic laboratory tests granted waived status under CLIA.

1.12.3.2 Clinical diagnostic laboratory tests considered to be CLIA Certificate of Waiver tests are listed on the CLIA web site at http://www.hcfa.gov/medicaid/clia/cliahome.htm/. These are the only procedure codes that may be billed to the DMAP by a provider who holds a CLIA Certificate of Waiver.

NOTE: The DMAP does not cover any services relating solely to the treatment of infertility.

1.12.3.3 If there are specific product names or manufacturer listed, a provider who holds a CLIA Certificate of Waiver may only bill if the test is done using one of those specified. The modifier “QW” defined as “CLIA waived test” must be added to the procedure code when billing the DMAP for a waived test, using the specific product and manufacturer as listed.

1.12.4 CLIA Certificate for Provider-Performed Microscopy Procedures (PPMP)

1.12.4.1 A practitioner who holds a CLIA Certificate of PPMP may bill the DMAP for any clinical diagnostic laboratory test categorized as a PPMP.

1.12.4.2 Clinical diagnostic laboratory tests considered CLIA provider-performed microscopy procedures are listed in Appendix J. A provider who holds a CLIA Certificate for Provider-Performed Microscopy may bill the DMAP for these tests in addition to the Certificate of Waiver tests.

NOTE: The DMAP does not cover any services related solely to the treatment of infertility.

NOTE: The DMAP considers some provider-performed microscopy procedures to be part of the physician evaluation and management service. Therefore, they are not separately reimbursable by DMAP (refer to Appendix J for specific tests).

1.12.5 CLIA Certificate of Registration Tests

A practitioner who holds a CLIA Certificate of Registration may bill the DMAP for any clinical diagnostic laboratory test for which they have received CLIA certification.

1.12.6 Specific Billing Instructions

1.12.6.1 Refer to Appendix L for specific billing instructions for:

- Multiple Units of Service
- Pregnancy Tests

- Organ or Disease Oriented Panels Drug Testing
- Therapeutic Drug Assays Urinalysis
- Chemistry and Toxicology Hematology
- Immunology Microbiology

1.12.7 Reserved

1.13 Preventive Medicine

1.13.1 Periodic Evaluation and Management of a Healthy Individual

1.13.1.1 The Level I HCPCS procedure codes for periodic evaluation of a healthy individual requiring a comprehensive history, comprehensive examination, the identification of risk factors, and the ordering of appropriate laboratory/diagnostic procedures used by the DMAP are found in the Periodicity Schedule in Appendix O.

1.13.2 Routine Gynecological Evaluation

1.13.2.1 The procedure codes for routine gynecological evaluation are found in Appendix O. Only one routine gynecological evaluation can be paid per calendar year regardless of provider.

1.13.3 Preventive Medicine Restrictions

1.13.3.1 The following restrictions apply to both the interval history and examination related to the healthy individual and the routine gynecological evaluation.

1.13.3.1.1 The procedure codes for the periodic evaluation of a healthy individual and for routine gynecological evaluation found in Appendix O are the only codes that may be used for routine well encounters when the exam is performed in the absence of complaints. The diagnosis code must indicate a routine well encounter.

1.13.3.1.2 Codes for office or other outpatient services, consultation, emergency department services and home services are NOT to be used for routine well encounters. These codes are strictly for use when illness is present or the patient presents with complaints. A diagnosis code indicating the illness must be used.

1.13.3.1.3 None of the preventive medicine codes found in Appendix O may be used on the same day as office or other outpatient services, hospital inpatient services, consultations, emergency department services, nursing facility services and home services without additional explanation and documentation.

1.13.3.1.4 The frequencies noted above apply regardless of provider.

1.14 Surgery

1.14.1 Medically necessary surgeries are covered by the DMAP. It is the responsibility of the physician to determine and substantiate the medical necessity of the surgery in the patient's medical record. The DMAP does not require prior authorization for medically necessary surgeries (excluding transplants and bariatric surgeries). However, the DMAP will prior authorize surgical procedures when requested.

1.14.2 In some instances, surgeries may be performed solely for cosmetic reasons (e.g., breast augmentation, a face-lift, etc.) and are never considered medically necessary.

The DMAP does not cover these instances. Some surgeries, while considered cosmetic in nature, may be covered by the DMAP if they can be documented as being medically necessary. For example: The DMAP may cover a reduction mammoplasty if the primary reason for the procedure is to correct a medical problem. However, the DMAP will not cover the procedure if it is done solely to improve an individual's appearance. Refer to the General Policy Manual, Section I - Non-Covered Services for other examples.

1.14.3 The DMAP recognizes ICD-10-CM (International Classification of Diseases) diagnosis codes and CPT® (Current Procedural Terminology) procedure codes. The provider must use the diagnosis code that is directly related to the procedure code being billed. The procedure code billed must agree with the actual procedure performed.

1.14.4 Reserved

1.14.5 The DMAP considers payment for surgical procedures to include the operation per se and local anesthesia (if used). Payment also includes normal, uncomplicated pre-op and post-op visits related to the surgery.

1.14.6 The DMAP uses the following payment guidelines for multiple and diagnostic surgeries. Claims will be reimbursed according to these medical policy guidelines.

1.14.6.1 Multiple Surgery

Type of Surgery	Payment Methodology
Multiple major related surgical procedures (through one incision)	Medicaid fee for the primary surgical procedure only
Major unrelated surgical procedures	Medicaid fee for primary procedure and ½ of Medicaid fee for secondary procedures
Minor unrelated surgical procedures	Medicaid fee for primary procedure and ½ of Medicaid fee for secondary procedures
Multiple fractures	Medicaid fee for primary fracture and ½ of Medicaid fee for secondary fractures

1.14.6.2 Diagnostic Surgery

Type of Surgery	Payment Methodology
Diagnostic surgical procedure with related major surgery	Medicaid fee for primary procedure and ½ of Medicaid fee for secondary procedures
Diagnostic surgical procedure with unrelated major surgical procedures or unrelated diagnostic surgical procedures	Medicaid fee for primary procedure and ½ of Medicaid fee for secondary procedures
Diagnostic surgical procedure with another related diagnostic surgical procedure	Medicaid fee for primary diagnostic procedure only

1.14.6.3 Separate Procedures

Procedures designated in the CPT® as separate procedures are included in the reimbursement for the primary procedure unless performed alone. No additional payment will be made for a procedure designated as a separate procedure when performed at the same time or in immediate sequence with another procedure in the same operating room.

1.14.7 Billing Information

1.14.7.1 The DMAP reviews most claims for multiple surgeries and generally requires operative reports and occasionally requests additional supporting documentation to determine proper payment resolution. Before billing the DMAP, the provider must be sure that:

1.14.7.1.1 The procedure described in the operative note agrees with the actual definition of the HCPCS procedure code billed.

1.14.7.1.2 Individual HCPCS procedure codes are not used when there is a single code that describes the actual services rendered.

1.14.7.1.3 Multiple lines with the same HCPCS code are not billed. The total units and charges must be on one claim line. If the procedure is designated by the DMAP as bilateral, one unit must be billed using modifier 50. If procedure is not designated by the DMAP as bilateral, two units (no modifier) and charges for both procedures must be billed on one claim line.

1.14.7.1.4 The name of the surgeon and the date of procedure on the operative report matches the name of the billing surgeon and the date being billed.

1.14.7.1.5 Unlisted procedure codes are used only when there is not a valid code for the service rendered.

1.14.7.1.6 When billing unlisted procedure codes, an operative report and/or supporting documentation must be attached to the claim.

1.14.7.1.7 When an assistant/co-surgeon is used, an operative report must be attached to the claim to ensure proper payment determination.

1.14.7.1.8 The appropriate modifier code is selected when an assistant/co- surgeon performs the procedure.

1.14.8 Transplants

1.14.8.1 The DMAP will review requests for coverage of the following transplants;

1.14.8.1.1 Heart

1.14.8.1.2 Heart/Lung

1.14.8.1.3 Liver

1.14.8.1.4 Bone Marrow and Peripheral Blood Stem Cell

1.14.8.1.5 Pancreas

1.14.8.1.6 Kidney

1.14.8.1.7 Intestinal (small bowel)

1.14.8.1.8 Cornea

1.14.8.1.9 Any other transplants DMAP determines to be added to the list of medically necessary organ and tissue transplantation procedures.

1.14.8.2 The attending specialist and the admitting facility must request prior authorization by sending a letter with the following information:

1.14.8.2.1 Type of transplant, including detailed information, i.e., method proposed, expected outcome, etc. Diagnosis, prognosis, and a brief outline of all medical problems, history, and indications for transplant

1.14.8.2.2 Documentation must be provided by the appropriate attending specialist and admitting facility that all of the following conditions are met: The facility performing the transplant must have approval for performing the surgery through the Certificate of Need (CON) process and must supply supporting documentation of this.

1.14.8.2.3 Current medical therapy has failed and will not prevent progressive disability and death.

1.14.8.2.4 The patient does not have other major systemic disease that would compromise the transplant outcome.

1.14.8.2.5 There is every reasonable expectation, upon considering all the circumstances involving the patient, that there will be strict adherence by the patient to the long-term difficult medical regimen that is required.

1.14.8.2.6 The transplant is likely to prolong life for at least two years and to restore a range of physical and social function suited to activities of daily living.

1.14.8.2.7 The patient is not both in an irreversible terminal state (moribund) and on a life support system.

1.14.8.2.8 The patient has a diagnosis appropriate for the transplant.

1.14.8.2.9 The patient does not have multiple non-correctable severe major system congenital anomalies.

1.14.9 Bariatric Surgery

1.14.9.1 The DMAP may cover bariatric surgery for treatment of obesity in adults when the patient’s obesity is causing significant illness and incapacitation and when all other more conservative treatment options have failed.

1.14.9.2 All requests for bariatric surgery must be prior authorized. This includes the surgeon, assistant surgeon (if medically necessary), anesthesiologist, and facility.

1.14.9.3 Requests for prior authorizations of bariatric surgery must be submitted in writing.

1.15 Sleep Testing

1.15.1 The DMAP may cover Sleep Studies/Polysomnography for evaluation of sleep-related disorders.

1.15.2 Detailed medical history that documents the need for a Sleep Study/Polysomnography must be included with the prior authorization request.

1.15.2.1 The detailed medical history must include, but is not limited to: patient's complaints and symptoms, and the physician's findings.

1.15.2.2 Requests for polysomnography with initiation of continuous positive airway pressure therapy or bi-level ventilation must be submitted with the results of the original study.

2.0 Specific Criteria for Obstetricians/Gynecologists/Nursemidwives

2.1 Regulations Regarding Sterilization, Hysterectomies and Abortions

2.1.1 The DMAP reimburses for voluntary sterilization and medically necessary hysterectomies for eligible Medicaid members. A requirement for payment is that either a Consent Form or an Awareness Form must accompany each claim (whichever is appropriate).

2.1.2 It is the responsibility of the attending physician to:

2.1.2.1 Secure a properly executed form when a voluntary sterilization is requested or a hysterectomy is required

2.1.2.2 Furnish a completed copy of the Consent or Awareness Form to the hospital and anesthesiologist for their billing purposes

2.1.3 The DMAP will reimburse hospitals and physicians (including anesthesiologists) who perform a voluntary sterilization or hysterectomy if the procedure meets the criteria set by federal and state regulations for payment.

2.2 Voluntary Sterilization - Consent Form

When a voluntary or elective sterilization is performed, the provider is required to upload a Consent Form with the electronic claim form. The Consent Form is made up of four separate sections and each must be completed. See Appendix F for a copy of this document. The sections are:

2.2.1 Consent to Sterilization

The member must complete the nine blanks in this section. The member must be 21 years of age or older at the time of his/her signature. If the patient is not 21 years of age or older when signing the Consent Form, the service is not covered by the DMAP. This section must be signed and dated by the member between six months and 30 days prior to the procedure.

1) Doctor or Clinic	The member must enter the name of the doctor or clinic that provided information about sterilization.
2) Sterilization Procedure	The member must enter the medical name of the sterilization procedure.
3) Birth date	The member must enter the month, day and year of his/her birth.
4) Name of Member	The member must enter his/her full name.
5) Name of Physician	The member must enter the name of the physician who will perform the sterilization procedure.
6) Sterilization Procedure	The member must enter the medical name of the sterilization procedure.
7) Signature	The member must sign the Consent Form.
8) Date	The member must enter the date the Consent Form was signed. This date must be between six months and 30 days prior to the procedure.
9) Race/Ethnicity Designation	The member is requested to supply the race and ethnicity designation, but it is not required.

2.2.2 Interpreter's Statement

If the member is not able to read/write/understand the English language, an interpreter must be present to translate the information presented on the Consent Form orally. The interpreter must complete the three blanks of the Interpreter's Statement.

This section should be left blank if the member is conversant in the English language and there is no interpreter.

10) Language	The interpreter must enter the language used in translating the information to the member
11) Interpreter	The interpreter must sign this statement.
12) Date	The interpreter must enter the date the Interpreter's Statement was signed.

2.2.3 Statement of Person Obtaining Consent

The six blanks in this section must be completed by the physician or the physician's nurse. The Statement of Person Obtaining Consent acknowledges that the nature of the sterilization procedure has been fully explained to the member. This section must be completed at the same time the member completes the Consent to Sterilization section.

13) Name of Individual	The physician or the nurse must enter the name of the member who signed the Consent Form
14) Sterilization Procedure	The physician or the nurse must enter the medical name of the sterilization procedure
15) Signature of Person Obtaining Consent	The physician or the nurse who counseled the member and explained to him/her the nature of the sterilization operation must sign on this line
16) Date	The physician or the nurse must enter the date consent was obtained. This date must be the same as the date of the member's signature in Blank 8
17) Facility	The physician or the nurse must enter the name of the facility where consent was obtained
18) Address	The physician or the nurse must enter the complete address of the facility where consent was obtained

2.2.4 Physician's Statement

The physician must complete the five blanks of this section. The Physician's Statement must be signed and dated on or after the date of service. The claim will be denied if the Consent Form is dated prior to surgery. Further, the date of sterilization in this section must match the date of service indicated on the claim form when billing the DMAP.

19) Name of Individual to be Sterilized	The physician must enter the name of the member who elected sterilization. This name must match the name of the member who signed Blank 7 of the Consent Form.
20) Date of Sterilization	The physician must enter the date that the sterilization procedure was performed.
21) Specify Type of Operation	The physician must enter the medical name of the sterilization procedure.
22) Select Appropriate Paragraph	The physician must cross out the paragraph that is NOT used. If paragraph 2 is chosen, indicate premature delivery and the individual's expected date of delivery or emergency surgery and description of the circumstances.
23) Signature Date	The physician must sign and date the Consent From. Signature stamps are not acceptable. This form must be signed and dated after the sterilization is performed.

2.3 Hysterectomies - Awareness Form

2.3.1 The Awareness Form is required for medically necessary hysterectomy procedures. There are no age limitations for the patient when the Awareness Form is completed. See Appendix G for a copy of this document. The following information must be completed on the Awareness Form.

1) Patient's Name	Enter the full name of the member.
2) Medicaid Number	Enter the member's Medical Assistance ID number.
3) Date of Surgery	Enter the date the surgery was (or is to be) performed.
4) Physician's Name	Enter the name of the physician performing the surgery.
5) Surgical Procedure	Enter the medical name of the surgical procedure.

Either Section A or Section B must be completed.

2.3.2 Section A

This section must be completed when the medical procedure results in sterilization. This section must be signed and dated by the member prior to, but no more than six months before, the procedure.

2.3.2.1 Patient Acknowledgment

6) Date	The member must enter the date the patient acknowledgment was signed. This date must be prior to, but no more than six months before, the procedure.
7) Patient's Signature	The member must sign the patient acknowledgment.

8) Date	If the member is not able to read/write/understand the English language, an interpreter must be present to translate the information presented on the Awareness Form orally. If applicable, the interpreter must enter the date the patient acknowledgment was signed.
9) Interpreter's Signature	If applicable, the interpreter must sign the patient acknowledgment.

2.3.2.2 Physician Certification

10) Patient's Name	The physician must enter the name of the member.
11) Date	The physician must enter the date the Awareness Form was signed. This date must be prior to, but no more than six months before, the procedure.
12) Physician's Signature	The physician must sign the Awareness Form. Signature stamps are not acceptable.

2.3.3 Section B

This section must be completed when the patient was previously sterile, or when the patient requires a hysterectomy because of a life-threatening emergency situation in which the physician determined prior acknowledgement was not possible. When this section is used, it must be signed and dated by the physician. However, there is no time limitation for the physician's signature and Section B does not have to be signed and dated prior to surgery. When this section is used, the member's signature is not required.

13) Select Appropriate Statement	The physician must select and check the appropriate statement.
14) Date	The physician must date the Awareness Form.
15) Physician's Signature	The physician must sign the Awareness Form. Signature stamps are not acceptable.

2.4 Sterilization of the Mentally Challenged

2.4.1 In accordance with 42CFR Subsection 441, Subpart F - Sterilizations and the Delaware Budget Epilogue, Section 121(a)(ii), the DMAP does not reimburse for the sterilization of the mentally challenged.

2.4.2 Although the DMAP does not cover the sterilization of the mentally challenged, the appropriate parties may obtain this service through another source by petitioning the Court of Chancery in the county in which the person to be sterilized resides or in which the institution in which he/she resides is located.

2.5 Unilateral/Bilateral Sterilization Procedure Codes

Certain HCPCS procedure codes may describe a procedure which is performed for the purpose of voluntary sterilization or may describe a medically necessary procedure which may or may not

result in sterilization. Claims for these procedures must be accompanied by either an Awareness or Consent Form depending on the exact nature of the surgery. A unilateral procedure requires an Awareness Form while a bilateral procedure requires a Consent Form.

2.6 Procurement of Consent/Awareness Form

Consent and/or Awareness Forms may be obtained via logging into the secure Delaware Medical Assistance Portal for Providers at https://medicaid.dhss.delaware.gov/provider/Home/tabid/135/Default.aspx.

2.7 Abortions

2.7.1 Endangerment to Mother's Life

2.7.1.1 Federal regulation, 42 CFR 441.203, permits the DMAP to reimburse for abortions if the "life of the mother would be endangered by the pregnancy."

2.7.1.2 Effective November 13, 1997 Federal law enacted new Hyde Amendment requirements for federally-funded abortions. One of those requirements is that, in order for Medicaid to reimburse for an abortion, a physician must certify that a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused or arising from the pregnancy itself that would place the woman in danger of death unless an abortion is performed.

2.7.1.3 A physician must complete an Abortion Justification Form (see Appendix M) that will detail the new Hyde Amendment requirement. In addition to the Abortion Justification Form the physician must attach the complete medical record to the CMS 1500.

2.7.1.4 It is the responsibility of the attending physician to supply a copy of the Abortion Justification Form and the complete medical record to the hospital and the anesthesiologist for their billing purposes.

2.7.2 Rape or Incest

2.7.2.1 Effective December 31, 1993, in compliance with the Hyde Amendment provision, the DMAP may reimburse for abortions to terminate pregnancies resulting from an act of rape or incest.

2.7.2.2 The practitioner must submit a letter stating that the request for the abortion is due to rape or incest and provide written documentation that the incident was reported to the police. In cases of incest where the victim is under 18 years of age, the incident must also have been reported to the Department of Services for Children, Youth and their Families.

2.7.2.3 If an adult has just cause for not reporting a rape to the police, the practitioner must document the reason in writing. The DMAP will consider coverage on a case-by-case basis.

2.7.3 Mifepristone, oral (RU-486) and Misoprostal, oral

2.7.3.1 The DMAP will reimburse practitioners for the drugs mifepristone (RU-486) and misoprostol only as abortive agents.

2.7.3.2 The drugs and related services are covered only if the Federal criteria for abortion are met. If the criteria are not met, the abortion and all related services will not be covered. These services include, but are not limited to, office visits, ultrasounds, blood/lab work, etc.

2.7.3.3 When billing the DMAP, the practitioner must use the appropriate Abortive Agent HCPCS code. These drugs will not be dispensed by a pharmacy as abortive agents.

2.7.3.4 The practitioner must complete the Abortion Justification Form and attach it and the complete medical record to the electronic claim.

2.8 Gynecological Evaluation-Related to the Healthy Individual

Refer to the Preventive Medicine segment under General Information for a complete outline of coverage and restrictions.

2.9 Antepartum Visits

2.9.1 Practitioners must bill for antepartum care separately from the delivery.

2.9.2 Office visits made to the Obstetrician/Gynecologist/Midwife during pregnancy for sick reasons unrelated to pregnancy may be billed under the appropriate level of office visit. The ICD-10-CM diagnosis code must correctly indicate the illness for which treatment was sought.

2.10 Family Planning Services

2.10.1 It is particularly important that any services provided which are primarily family planning in nature be properly indicated.

2.10.2 Since the State receives a larger federal dollar match for family planning services than for other types of medical care, proper coding of both the diagnosis, procedure and modifier will result in a financial savings in terms of state funds necessary to support the DMAP.

2.11 Fertility Related Services

2.11.1 The DMAP does not cover any services relating solely to the treatment of infertility. Examples of these non-covered services include:

2.11.1.1 Drug therapy.

2.11.1.2 Surgical procedures (for example: reversal of sterilization).

2.11.1.3 Laboratory testing.

2.11.1.4 Radiology services.

2.11.1.5 Hospital services.

2.11.1.6 Physician services.

2.12 Billing

When billing the DMAP, the physician/nurse-midwife must use the appropriate CPT® procedure codes.

3.0 Specific Criteria for Urologists

3.1 Regulations Regarding Sterilization For Males

3.1.1 The DMAP reimburses for voluntary sterilization for eligible Medicaid members who are over twenty-one years of age. A requirement for payment is that a Consent Form must accompany each claim.

3.1.2 It is the responsibility of the attending physician to:

3.1.2.1 Secure a properly executed form when a voluntary sterilization is requested

3.1.2.2 Furnish a completed copy of the Consent Form to the hospital and anesthesiologist for their billing purposes

3.1.3 The DMAP will reimburse hospitals and physicians (including anesthesiologists) who perform a voluntary sterilization if the procedure meets the criteria set by federal and state regulations for payment

3.1.4 See the Specific Criteria for Obstetricians/Gynecologists/Midwives for instructions on how to complete the Consent Form.

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4.0 Specific Criteria for Practitioners Who Treat Children

4.1 Well-child Visits

The DMAP will pay for well-child visits to coincide with the general practice of pediatrics. Refer to the Preventive Medicine segment under General Information for a complete outline of coverage and restrictions.

4.1.1 Oral Health Assessment and Fluoride Varnish for Medical Providers

Section 4106 of the Affordable Care Act (ACA) requires that Medicaid cover "any clinical preventive services that are assigned a grade A or B by the United States Preventive Services Task Force" (USPSTF). The Centers for Medicare and Medicaid Services (CMS) encourages state Medicaid and CHIP programs to reimburse medical providers for children's oral health services such as risk assessment, fluoride varnish, and anticipatory guidance.

The recommendation is available on the USPSTF website: https://uspreventiveservicestaskforce.org/uspstf/

4.1.1.1 Effective July 1, 2015 the DMAP will reimburse approved medical providers for the topical application of fluoride varnish.

Effective January 1, 2016 this service was added to the Managed Care Organization (MCO) benefit. The following conditions apply:

- one time in six months,
- and when completed on the same day as an approved Medicaid well-child visit for children between the ages of six months through age five.

4.1.1.2 Only Physicians, Physician Assistants, Advanced Practice Registered Nurse, Clinical Nurse Specialists and Registered Nurses (bachelor's degree) who successfully complete the Smiles for Life Fluoride Varnish course (Course 6: Caries Risk Assessment, Fluoride Varnish and Counseling) at www.smilesforlifeoralhealth.org are permitted to complete the oral health screening and apply the fluoride varnish.

4.1.1.2.1 Each provider must maintain documentation of successful completion of approved training and continuing education.

4.1.1.2.2 Providers can obtain free oral health pamphlets by contacting the Division of Public Health at http://www.dhss.delaware.gov/dhss/dph/index.html and order oral health materials from at https://catalog.nidcr.nih.gov/OrderPublications/

4.1.1.3 Reimbursement for fluoride varnish includes the oral health screening, completion of The Oral Health Risk Assessment Tool, oral health instructions and referral to a dental home for children who are at high or moderate risk for poor oral health.

4.1.1.3.1 Medical providers are required to:

4.1.1.3.1.1 Refer children to see a dentist by their first birthday and;

4.1.1.3.1.2 Refer members to a Medicaid participating dental provider for coordination of care (Link to list of Medicaid dental providers, see providers age limitations), http://www.dmap.state.de.us/information/DE_participating_oral_health_providers1.pdf

Proceed with coordination of care by referring members to a Medicaid participating dental provider and notifying selected dental provider the date that the service has been performed. (Link to list of Medicaid dental providers, see providers age limitations), http://www.insurekidsnow.gov/state/delaware/delaware_oral.html

4.1.1.3.1.3 Check member eligibility to verify that the topical fluoride treatment or fluoride varnish was not completed with-in the last six months by another medical or dental provider.

4.1.1.3.1.4 Counsel and provide educational materials on good oral hygiene practices and nutrition to guardians and members.

4.1.1.3.1.5 Document early caries screening and detection of findings

4.1.1.3.1.6 Prescribe a fluoride supplement as indicated, per guidelines from the American Academy of Pediatrics (www.aap.org)

4.1.1.3.1.7 Present member or guardian with documented date of service of treatment to present to dental provider and maintain for own records.

4.1.1.3.1.8 Maintain records for a minimum five years from the date of service.

4.1.1.4 Billing Procedures for Fluoride Varnish:

4.1.1.4.1 Billing for MCO covered members.

Fluoride varnish must be billed to the MCO for reimbursement. The well child visit must be billed to the MCO also.

4.1.1.4.2 Billing for DMAP covered members.

Fluoride varnish must be billed to the DMAP for reimbursement. The well child visit must be billed to the DMAP also.

4.1.1.4.3 This service is covered one time in six months and must be completed on the same visit as a Medicaid well-child visit, using CPT® code 99188.

4.1.1.4.4 In the comment section of the electronic claim submission include the certificate serial number for the Smiles for Life Course 6 and indicate one of the following codes D0601- low caries risk, D0602- Moderate caries risk, D0603- High caries risk based upon your oral health assessment.

4.2 Stand-by During Caesarean Section

The DMAP will make payments to a pediatrician who stands-by during a caesarean section. The correct way to bill for this procedure is to use the appropriate Level I HCPCS procedure code listing the mother as the patient and using the mother's ID number.

4.3 Reserved

4.4 EPSDT Services and Guidelines

DMAP Policy follows Bright Futures/American Academy of Pediatrics Guidelines, for Health Supervision of Infants, Children, and Adolescents.

EPSDT services at a minimum should be provided seven (7) times before a child's first year of life, five (5) times before the age of three (3) and annually from ages two through five, as prescribed by the EPSDT Periodicity Schedule and should include:

4.4.1 Comprehensive Health and Development History must be obtained from the parent or other responsible adult who is familiar with the child's medical history and must include an assessment of both physical and mental health development.

4.4.2 Developmental Assessment is an array of activities to determine whether a child's developmental progress falls within a normal range of achievement according to age group and cultural background. Developmental screening must be a part of every routine initial and periodic examination.

4.4.2.1 In preschool children, at least the following assessments must be done:

4.4.2.1.1 Gross motor development, focusing on strength, balance, locomotion

4.4.2.1.2 Fine motor development, focusing on eye-hand coordination

4.4.2.1.3 Communication skills and language development, focusing on expression, comprehension and speech articulation

4.4.2.1.4 Self-help and self-care skills

4.4.2.1.5 Social-emotional development, focusing on the ability to engage in social interaction with other children, adolescents, parents or other adults

4.4.2.1.6 Cognitive skills, focusing on problem solving or reasoning.

4.4.2.1.7 Objective developmental testing is recommended from three months through four years of age. Suggested examples of tests which are reliable, valid and culturally sensitive for this age group include, but are not limited to, the following:

- Revised Denver Prescreening Developmental Questionnaire (R-PDQ);
- Denver Developmental Screening Test II (DDST II);
- Minnesota Child Development Inventory

4.4.2.2 As the child goes through school age, the focus of a developmental assessment must be on visual-motor integration, visual-special organization, visual sequential memory, attention skills, auditory processing skills, and auditory sequential memory.

4.4.2.3 For adolescents, the orientation should encompass such areas of special concern as potential presence of learning disabilities, peer relationships, psychological or psychiatric problems and vocational skills.

4.4.2.4 The developmental assessment must be culturally sensitive and valid. Potential problems should not be dismissed or excused improperly on grounds of culturally appropriate behavior, nor should referrals be initiated improperly for factors associated with cultural heritage.

4.4.2.5 EPSDT screening programs should not label or result in a premature diagnosis of a child. Providers should report only that a condition was referred or that a type of diagnostic or treatment service is needed. Results of initial screenings should not be accepted as conclusions and do not represent a diagnosis.

4.4.3 Assessment of Nutritional Status can be obtained in the basic examination through:

4.4.3.1 Questions about dietary practices to identify unusual eating habits (such as pica or extended use of bottle feedings) or diets which are deficient or excessive in one or more nutrients.

4.4.3.2 A complete physical examination includes a dental examination. Special attention should be paid to such general features as pallor, apathy and irritability.

4.4.3.3 Accurate measurements of height and weight.

4.4.3.4 A laboratory test to screen for iron deficiency. CMS and the Public Health Service recommend that the erythrocyte protoporphyrin (EP) test be utilized when possible for children ages one through five years.

4.4.3.5 If feasible, screen children over age one for serum cholesterol determination, especially those with a family history of heart disease and/or hypertension and stroke.

4.4.3.6 If information suggests dietary inadequacy, obesity or other nutritional problems, further assessment is indicated, including:

4.4.3.6.1 Family, socioeconomic or any community factors

4.4.3.6.2 Determining quality and quantity of individual diet (e.g., dietary intake, food acceptance, meal patterns, methods of food preparation and preservation, and utilization of food assistance programs)

4.4.3.6.3 Further physical and laboratory examinations

4.4.3.6.4 Preventive, treatment and follow-up services including nutritional counseling and education

4.4.3.6.4.1 For children 3 years and older with a qualifying diagnosis and a BMI > 85th percentile, referral to an intensive behavioral therapy for obesity

4.4.4 Comprehensive Unclothed Physical Examination includes the following:

4.4.4.1 Physical Growth The child's height and weight must be recorded and compared with those considered normal for that age. (In the first year of life, head circumference measurements are important.) Use a graphic recording sheet to chart height and weight over time.

4.4.4.2 Unclothed Physical Inspection The general appearance of the child must be checked to determine overall health status. This process should pick up obvious physical defects, including orthopedic disorders, hernia, skin disease, and genital abnormalities. Physical inspection includes an examination of all organ systems such as pulmonary, cardiac and gastrointestinal. The exam should allow for complete inspection, auscultation, and palpation of the major organ systems while providing for the child’s privacy and comfort.

4.4.4.3 Recommended Childhood Immunizations should be administered according to the yearly schedule approved by the Advisory Committee on Immunization Practices (ACIP). This schedule includes recommendations for Hepatitis B, Diphtheria, Pertussis, H. Influenzae (type b), Inactivated Polio, Pneumococcal Conjugate measles, Mumps, Rubella, Varicella, and Hepatitis A in selected areas.

4.4.5 Appropriate Laboratory Tests should include, but not be limited to:

4.4.5.1 Lead toxicity screening – All children are considered at risk and must be screened for lead poisoning. A blood lead test must be performed for all Medicaid children using the following schedule:

- First screening at 12 months of age
- Second screening at 24 months of age
- Screening of all Medicaid children between 36 and 72 months of age, who have not been screened previously
- Blood lead screening during the child's pre-school or pre- kindergarten physical, if there is no documentation that a test was performed prior to that age.

4.4.5.1.1 In addition, risk exposure status should be monitored and updated at each physician/nurse practitioner visit using the Childhood Lead Poisoning Prevention Risk Questionnaire (Appendix C of the Division of Public Health Lead Poisoning Prevention Guidelines). Additional blood lead testing should be repeated as appropriate.

4.4.5.1.2 The initial blood-lead screening test may be performed by venipuncture or by fingerstick, Initial fingerstick test results >10□g/dL must be confirmed by venipuncture. For detailed information regarding blood- lead testing procedures refer to the DPH Lead Poisoning Prevention Guidelines or call the Delaware Helpline.

4.4.5.2 Hematocrit (HCT) or hemoglobin (Hgb) testing is recommended at the preferred ages of 12 months for initial screening, 15 months – 5 years of age for members at risk and annual screening for all adolescents at risk.

4.4.5.3 Reserved

4.4.5.4 Other laboratory screening tests such as urinalysis, Tuberculin skin testing, Cholesterol screening, and STD screening are to be performed for members at risk. Practitioners are to use their medical judgement in determining the applicability of such laboratory testing or analyses.

4.4.5.5 Reserved

4.4.6 Health Education and Anticipatory Guidance must be provided at each EPSDT exam. This activity should focus on both parent and child and should be integrated throughout the encounter. Health education and anticipatory guidance should help the family understand what to expect in terms of the child's development, and provide information about the benefits of healthy lifestyles and practices as well as accident and disease prevention.

4.4.7 Vision and Hearing Screens should be done six times during the first year of life, three times between ages one and two, and annually thereafter. Whenever practical, these screens should be scheduled to coincide with the overall physical/mental screen.

4.4.8 Oral Health Screening and Treatment

4.4.8.1 Primary care medical providers should include an oral health assessment as part of the well-child check-up throughout childhood, starting at six months of age. All providers should refer children to a Medicaid Dental Provider by age one for routine

maintenance and education. Link to Medicaid participating dental providers for referrals. https://medicaid.dhss.delaware.gov/provider/Home/DentalCornerLanding/

4.4.9 Dental services include the relief of pain and infection, restoration of teeth, and maintenance of dental health. Refer to the Children's Dental Program Provider Specific Policy Manual for a list of all covered EPSDT dental services. https://medicaid.dhss.delaware.gov/provider/Home/DentalCornerLanding

5.0 Specific Criteria for Anesthesiology Procedures

5.1 Procedure Coding

The anesthesiology provider must bill the DMAP with codes listed under Anesthesia in the CPT® book. When multiple surgical procedures are performed during a single anesthetic administration, the anesthesiologist must use the CPT® procedure code of the primary anesthesia procedure only.

5.2 Placement of a Swan-Ganz Catheter

An anesthesiology provider who inserts a Swan-Ganz catheter during the administration of anesthesia may bill one unit of the appropriate procedure code in addition to the procedure code of the primary anesthesia procedure. No time units may be billed for the placement of a Swan-Ganz catheter as these time units are included in the primary anesthesia procedure. All other specialized forms of monitoring are included in the base units and are not billable separately.

5.3 Preoperative Evaluations

Preoperative evaluations for anesthesia are included in the fee for administration of anesthesia and the anesthesiology provider may not bill them as consultations. A consultation may be billed only when the case does not proceed to anesthetic administration and supportive documentation to verify this fact must be attached to the electronic claim.

Example: When a preoperative evaluation for anesthesia is done on a woman in labor who delivers by caesarean section, the anesthesiology provider may NOT bill a consultation. However, when a preoperative evaluation for anesthesia is done on a woman in labor who has natural childbirth with no anesthesia, the anesthesiology provider may bill consultation reflective of the level of service provided. The anesthesia notes as well as hospital records verifying the circumstances must accompany the invoice.

5.4 Base Units

5.4.1 Each anesthesia procedure code has “base units” specific to that procedure code. These base units for anesthesia services are built into the procedure code. All care including usual pre-operative and post- operative visits, the administration of fluids and/or blood incident to the anesthesia care and all monitoring procedures other than the placement of a Swan-Ganz catheter are included in the base units.

5.4.2 The anesthesiology provider does NOT indicate base units when completing the claim form.

5.5 Time Units

5.5.1 “Time Units” are defined as 1 minute of elapsed time (one time unit = 1 minute). Anesthesia time starts when the anesthesiology provider begins to prepare the patient for anesthesia care in the operating room and ends when the anesthesiology provider is no longer in personal attendance, that is, when the patient may be safely placed under post operative supervision. These time units must be clearly documented in the anesthesia record.

5.5.2 The anesthesiology provider must indicate the time units on the claim form. Payment will be made based on the time units billed, divided by 15 and added to the base units already incorporated in the specific procedure code. It is important, therefore,

to bill using the correct procedure code and to only enter the time units (1 time unit per every 1 minute of elapsed time).

5.6 Sterilization Procedures

When billing for sterilization/hysterectomy anesthesia procedures, the anesthesiology provider must attach a Consent or Awareness Form to the electronic claim. It is the responsibility of the attending physician to forward the appropriate form to the anesthesiology provider. The DMAP does not cross-reference claims and forms.

5.7 Billing Procedures for Independent Certified Registered Nurse Anesthetists (CRNA)

5.7.1 Independent Certified Registered Nurse Anesthetists may only bill for services performed without physician supervision.

5.7.1.1 All services billed by an independent CRNA must be billed with a modifier QZ (CRNA Service: Without Medical Direction by a Physician) to document that the service was performed without supervision.

5.7.2 At the time of enrollment, anesthesiology providers must provide a list of anesthesia procedure codes (00100-01999) for the services they provide and will only be reimbursed for those procedures. Updates to this list may be made by contacting the DMAP Fiscal Agent, Provider Relations.

6.0 Specific Criteria for Ophthalmologists and Optometrists

6.1 Age Restrictions

6.1.1 Routine eye care that encompasses routine eye exams including refraction and the provision of eyeglasses is restricted to DMAP members who are under twenty-one (through age 20) years of age. The following policies apply:

6.1.1.1 A routine eye exam including refraction will be paid once per year unless a medical condition exists that warrants more frequent exams.

6.1.1.2 Lenses and/or frames may be dispensed only when medically necessary. The DMAP will cover replacement of damaged lenses and/or repair of broken frames.

6.1.1.3 A provider is prohibited from splitting the cost of lenses or the cost of frames between the DMAP and the Medicaid member.

Example: If the member wants a special frame for cosmetic reasons, the member must be informed that the DMAP does not cover this service and the member is expected to pay in full for the frame. However, the DMAP will pay for the standard lenses.

Example: If the member wants special photogrey lenses for cosmetic reasons, the member must be informed that the DMAP does not cover this service and the member is expected to pay in full for the lenses. However, the DMAP will pay for the standard frames.

Example: If the member wants special photogrey lenses and special frames for cosmetic reasons, the member must pay in full for the entire pair of eyeglasses.

6.1.2 Providers are reminded that the DMAP payment is considered to be payment in full.

6.2 “Sick” Eye Office Visits

6.2.1 The DMAP defines a “sick” eye office visit as an evaluation and management service for eye conditions such as conjunctivitis, corneal abrasions, iritis, glaucoma, cataracts, etc. A “sick” eye visit is not a routine evaluation for refractive errors such as hyperopia, myopia or astigmatism.

6.2.2 The DMAP will reimburse ophthalmologists and optometrists for “sick” eye visits. There is no age restriction for this service.

6.3 Prior Authorization

6.3.1 The DMAP is based on providing medically necessary services in the most appropriate, cost-efficient manner. Some services require prior authorization before a payment can be made to the provider. The provider must submit a letter that includes documentation of medical necessity to the Medical Review Team. Documentation required for prior authorization of specific ocular services is listed below. Documentation that must be submitted for all requests includes: Patient’s name; medical assistance ID number; date of birth; diagnosis/prognosis; procedure code and all applicable charges.

6.3.2 Documentation should be submitted to P.O. Box 906 Lewis Building, New Castle, DE 19720. If approval is given, the billing provider will receive a prior authorization number along with notice of the DMAP payment amount.

6.3.3 The following ocular services require prior authorization:

6.3.3.1 Contact Lenses

6.3.3.1.1 The DMAP may cover contact lenses to improve visual acuity or to treat ocular conditions such as keratoconus, corneal dystrophy and aphakia. Contact lenses used solely to improve visual acuity are covered only for individuals under the age of 21 years when correction cannot be achieved with eyeglasses.

6.3.3.1.2 Additional documentation for prior authorization for contact lenses must include: Results of vision test; statement of medical necessity for contact lens; specific contact lens type and prescription.

6.3.3.2 Specialty Bifocals

6.3.3.2.1 The DMAP may cover specialty bifocal lenses for individuals under the age of 21 years when documentation is submitted for review of medical appropriateness.

6.3.3.2.2 Additional documentation for prior authorization for specialty bifocals must include: Results of vision testing; statement of medical necessity detailing why standard bifocals are not sufficient; specific lenses and prescription.

6.3.3.3 Trifocals

6.3.3.3.1 The DMAP may cover trifocal lenses for individuals under the age of 21 years when documentation is submitted for review of medical appropriateness.

6.3.3.3.2 Additional documentation for prior authorization for trifocal lenses must include: Results of vision testing; surgical report (if applicable); statement of medical necessity detailing the need for trifocals; specific lenses and prescription.

6.3.3.4 Variable Asphericity Lenses

6.3.3.4.1 The DMAP may cover variable asphericity lenses for individuals under the age of 21 years for prescriptions greater than or equal to 12 diopters.

6.3.3.4.2 Additional documentation for prior authorization for variable asphericity lenses must include: Results of vision testing; prescription for spectacle lenses.

6.3.3.5 Deluxe Frame

6.3.3.5.1 The DMAP may cover a deluxe frame for special needs children, for infant eye size under 42mm, for a child eye size over 58mm and for safety reasons.

6.3.3.5.2 Additional documentation for prior authorization for deluxe frames must include: Diagnosis with additional information about functional limitations and safety issues, (if applicable); statement of medical necessity indicating specific reasons that a deluxe frame is needed; specific type of frame; and a copy of the company's invoice that describes the item and gives an itemized explanation of all charges.

6.3.3.6 Scratch Resistant Coating

6.3.3.6.1 The DMAP may cover scratch resistant coating (SRC) for lenses when medically necessary.

6.3.3.6.2 Additional documentation for prior authorization for scratch resistant coating must include: Statement indicating specific reasons that SRC is needed.

6.3.3.7 **Medically Necessary Services not described by CPT® or HCPCS codes and billed using (V2799) Vision Services, Miscellaneous**

6.3.3.7.1 The DMAP may cover services not described by CPT® or HCPCS codes when medically necessary.

6.3.3.7.2 Additional documentation for prior authorization for miscellaneous vision services must include: Description of the service being requested; statement of medical necessity

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7.0 Specific Criteria for Radiology Procedures

7.1 Billing Procedures

7.1.1 A physician using Level I HCPCS procedure codes in the 70000 series may bill for the professional component only or for the entire procedure (both the technical and the professional component).

7.1.1.1 If the physician is billing for the entire procedure (both the technical and the professional component), this indicates that the physician owns the x-ray equipment, supplies all necessary materials including the contrast medium, employs the technician, and provides the professional services.

7.1.1.2 If the physician is billing for the professional component only, this indicates that the technical component is billed by the facility and that the physician is billing only for his/her professional services. Hospital based physicians must bill for the professional component only.

7.2 Precautions

7.2.1 Providers are reminded to choose their procedure codes carefully with the following cautions in mind:

7.2.1.1 Do not use multiple procedure codes when a single procedure code accurately describes the services rendered.

7.2.1.2 Some codes specify bilateral or unilateral. Be sure to utilize a code that correctly indicates this factor.

7.2.1.3 Some codes specify the number or type of views done. Be sure to choose a code that correctly describes your procedure.

7.2.1.4 Pay close attention to codes where contrast material is used. Is the study with contrast? Without contrast? Or without contrast material, followed by contrast material and further sections?

7.3 Prior Authorization

7.3.1 Positron Emission Tomography (PET) Scans

7.3.1.1 All PET scans require prior authorization

7.3.1.2 PET scans will be provided in accordance with Section 50-36 of the Medicare Coverage Issues Manual. Refer to Appendix P of this manual for Section 50-36 of the Medicare Coverage Issue Manual.

7.3.1.3 Prior authorization must be requested by the referring physician and must include:

7.3.1.4 Results of previous tests (Pathology/biopsy reports, CT scan, MRI, ultrasound, x-ray, previous stress tests, etc.)

7.3.1.5 Detailed medical history that documents the need for PET scan

7.3.2 Computed Tomographic Colonography

7.3.2.1 The DMAP may cover computed tomographic colonography in the following instances:

7.3.2.2 For colonic evaluation of symptomatic patients with a known colonic obstruction

7.3.2.3 For patients with an incomplete colonoscopy due to obstructive or stenosing colonic lesions

7.3.2.4 For patients who are receiving chronic anticoagulation therapy that cannot be interrupted

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8.0 Specific Criteria For Podiatrists

8.1 Billing Procedures

8.1.1 The DMAP reimburses for routine foot care ONLY for members who are diagnosed as having diabetes or circulatory/vascular disorders of the lower extremities.

8.1.2 The following procedures define routine foot care:

8.1.2.1 Trimming of nondystrophic nails, any number

8.1.2.2 Debridement of nails(s) by any method(s); one to five

8.1.2.3 Debridement of nail(s) by any method(s); six or more

8.1.3 The DMAP does not reimburse podiatrists for evaluation and management services provided to patients in nursing facilities. The DMAP will reimburse podiatrists for medically necessary procedures performed on patients in nursing facilities.

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9.0 Specific Criteria for Oral Surgeons

9.1 Billing Procedures

9.1.1 Dental services are available to DHCP members under 19 (through age 18) years of age, and Medicaid and EPSDT members under 21 (through age 20) years of age. Dental services are also available to adults 21 years and older under the Adult Dental Program.

9.1.1.1 Prior authorizations may vary depending on the program for claim submission. Verify coverage and eligibility with each program separately.

9.1.1.2 Refer to the Children's Dental Manual for a list of all covered EPSDT dental services for individuals under age 21. Refer to the Adult Dental Manual for services pertaining to adults age 21 years and older. (https://Medicaid.dhss.delaware.gov/)

9.1.1.3 The removal of bony impacted wisdom teeth is excluded from the multiple surgery policy in Section 1.14.6.1. DMAP will provide reimbursement for each bony impacted wisdom tooth removed. Qualified providers must submit claim requests on the CMS-1500 claim form and submit CPT® code 41899 to be reimbursed for this service. Each unit must represent the removal of a bony impacted wisdom tooth. In the comment section of the claim, providers must enter the tooth number and the related ADA code. For example: Tooth 1 code D7240, Tooth 16 code D7230.

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10.0 Specific Criteria for Allergists

10.1 Billing for Allergy Injections

10.1.1 When billing for an allergy injection for dates of service on or after January 1, 2008, the following procedure should be followed:

10.1.1.1 The injectable substance is billed using the appropriate procedure code for preparation and provision of antigens.

10.1.1.2 The injection is billed using the appropriate allergen immunotherapy injection-only procedure code.

10.1.1.3 If a significant separately identifiable Evaluation and Management (E/M) service is performed on the same day as the allergy injection, the appropriate E/M service code should be reported using modifier 25.

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11.0 Specific Criteria for Plastic Surgeons

11.1 Billing Procedures

The DMAP does not reimburse any provider for cosmetic surgery. Cosmetic surgery is defined as beautification or aesthetic surgery designed to improve the appearance of an individual by surgical alteration of a physical characteristic that is within the broad range of normal.

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12.0 Specific Criteria for Hospital Based Emergency Room Physicians

12.1 Billing Procedures

12.1.1 When billing the DMAP, emergency room physicians must use emergency room CPT® codes. Emergency room physicians may also bill for any additional services provided using appropriate CPT® codes.

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13.0 Specific Criteria for Chiropractic Services

13.1 Member Eligibility

13.1.1 Providers must verify member eligibility by logging into the Delaware Medical Assistance Portal for Providers at https://Medicaid.dhss.delaware.gov/ or by using the Voice Response System (VRS) by calling 1-800-999-3371.

13.1.2 The DMAP will not cover eligible members for chiropractic services prior to October 1, 2014.

13.1.3 Effective January 1, 2018 chiropractic services was added as a Managed Care Organization (MCO) covered benefit.

13.2 Covered Services

13.2.1 Covered Services & Limitations

13.2.2 Chiropractic services are furnished in accordance with 42 CFR 440.60(b) and include only services that are provided by a chiropractor who is licensed by the State, and consist of treatment by means of manual manipulation of the spine that the chiropractor is legally authorized by the State to perform.

Manipulation and allowable adjunctive therapy per 24 Del Admin. Code Ch. 700 associated with the treatment of misaligned, fixated, or displaced vertebrae, including subluxation complex and other extraspinal (head, upper and lower extremities, rib cage, and abdomen) neuromusculoskeletal and soft tissue structures limited to one visit per member per day.

13.2.2.1 Manipulation and adjunctive therapy for Chronic Pain Management. Chiropractic Chronic Pain Management means continuous, interval-based long-term treatment that is necessary for patients with chronic pain and/or disease. This care includes but is not limited to treatment for patients who must resume care, notwithstanding having been discharged from chiropractic care as cured for any particular ailment, because that person's body is unable to sustain those results due to treatment withdrawal.

13.2.2.2 One office visit for the evaluation and management of services must be completed for each new patient. Additionally, evaluation and management services to document medical necessity and/or to determine progress or exacerbation may be performed on the same day as treatment and is considered a separate and distinct service.

13.2.3 Necessity for Treatment

The patient must have a significant health problem in the form of a neuromusculoskeletal condition necessitating treatment, and the manipulative and allowable adjunctive therapy services rendered must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery, improvement of function, or preventing deterioration of a chronic condition. The patient must have a spinal or extraspinal condition as demonstrated by x-ray or physical examination.

13.2.3.1 Acute pain and/or dysfunction – A patient's condition is considered acute when the patient is being treated for a new injury, identified by x-ray or physical examination.

The result of chiropractic manipulation and allowable adjunctive therapy is expected to be an improvement in, or arrest of progression, of the patient's condition.

13.2.3.2 Chronic pain and/or dysfunction – A patient's condition is considered chronic when it is not expected to significantly improve or be resolved with further treatment (as is the case with an acute condition), but where the continued therapy can be expected to result in some functional improvement or prevent deterioration of a chronic condition.

13.2.3.3 The necessity for care may be demonstrated by x-ray or physician's examination.

13.2.3.3.1 X-ray may be used to diagnose spinal or extraspinal conditions. If x-ray is used for this purpose, it must have been taken reasonably close to (within 12 months prior or 3 months following) the beginning of treatment. In certain cases of a chronic condition (e.g., osteoarthritis), an older x-ray may be accepted if the beneficiary's health record indicates the condition has existed longer than 12 months and there is a reasonable basis for concluding that the condition is permanent. A previous CT scan and/or MRI are acceptable evidence if a chronic condition of the spine or an extraspinal region is demonstrated. X-rays that support medical necessity and rule out pathology; the chiropractor may perform the x-rays in his or her office or refer patients for x-rays, MRI, CT scans and/or other allowed diagnostic tests per 24 Del Admin. Code Ch. 700 to a participating facility. X-rays may also be used for routine monitoring.

13.2.3.3.2 Physical exam to document spinal or extraspinal dysfunction, pain, or to determine progress; evaluation must be demonstrated by meeting two of the following four criteria, one of which must be asymmetry/misalignment identified on a sectional or segmental level below:

- Pain/tenderness evaluated in terms of location, quality and intensity;
- Asymmetry/misalignment identified on a sectional or segmental level;
- Range of motion abnormality (changes in active, passive, and accessory joint movements resulting in an increase or a decrease of sectional or segmental mobility);
- Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia, muscle, and ligament.

13.3 Non-Covered Services

13.3.1 Non-covered chiropractic services include the following:

- Vitamins;
- Minerals;
- Supplements;
- Chiropractic maintenance therapy is not considered to be medically necessary and is not covered when provided to Medicaid recipients who do not suffer from chronic pain and/or dysfunction and continued therapy can be expected to result in some functional improvement or prevent deterioration of a chronic condition.
- Any services outside of scope of state licensure.

- Room and Ward fees are not covered.
- Hand-held and other devices used for manipulation/adjustment are eligible for reimbursement, but there is no additional reimbursement amount that can be charged beyond the chiropractic manipulative therapy reimbursed amount published in the current DMMA Fee Schedule.

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14.0 Specific Criteria for Prosthodontists

14.1 Criteria

14.1.1 The DMAP will cover oral and facial prosthetics for eligible Medicaid members who are age 21 or older when determined to be medically necessary and part of a rehabilitation plan to treat an anatomical deficiency caused by disease, injury, or other diagnosed conditions.

14.2 Prior Authorization

14.2.1 The DMAP will reimburse a Prosthodontist for a medically necessary obturator only when the prosthetic is prior authorized and the related surgical process is prior authorized.

14.2.2 Providers treating MCO-enrolled Medicaid adults should seek approval from and bill the member's MCO directly.

14.3 Billing Procedure

14.3.1 When billing the DMAP for maxillofacial prosthetics the Prosthodontist shall use the appropriate CPT® code in the 210XX series.

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15.0 Specific Criteria for Psychiatrists

15.1 Billing Procedures

15.1.1 When billing the DMAP, psychiatrists must use the appropriate procedure code listed in the Psychiatry section of the CPT®.

15.2 Prior Authorization

15.2.1 Services for Transcranial Magnetic Stimulation require prior authorization and a referral from the treating Psychiatrist. Providers must submit the following documentation:

- Diagnosis of Major Depressive Disorder
- Inadequate response to pharmacotherapy to include of all of the following:
    - Adequate duration of dosage
    - Documented adherence
    - Trials from 2 or more classes of medications
- Negative history of cochlear implant, deep brain stimulator, or vagus nerve stimulator
- Negative history of epilepsy or history of seizure
- Negative history of metallic hardware or implanted magnetic- sensitive medical device (e.g., implanted cardioverter-defibrillator, pacemaker, metal aneurysm clips or coins at a distance within the electromagnetic field of the discharging coil (e.g., less than or equal to 30 cm to the discharging coil)

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16.0 Specific Criteria for Telehealth Services

16.1 Overview

16.1.1 Telehealth can be a cost-effective alternative to face-to-face in-person encounters under several circumstances, including where access to care is compromised due to the lack of available service providers in the patient's geographical location. This definition is modeled on Medicare's definition of telehealth services located at 42 CFR §410.78. Note that the Federal Medicaid statute (Title XIX of the Social Security Act) does not recognize telehealth as a distinct service.

16.1.2 The referring provider at the originating site and distant telehealth practitioner agree to all terms and conditions listed in the Delaware Medical Assistance Program (DMAP) contract and the policies and procedures in this manual.

16.1.3 The practitioner must follow all applicable state and federal regulations governing the use of telehealth including, but not limited to, 24 Del.C. Chapter 60.

16.1.4 For information regarding services and reimbursement for behavioral health services, providers must refer to the state regulations including, but not limited to, 16 Del.C.

16.2 Definitions

16.2.1 For purposes of DMAP, **telehealth** means the use of information and communication technologies consisting of telephones, remote patient monitoring devices, or other electronic means to provide or support health care delivery. It occurs when the patient is at an originating site and the health care provider is at a distant site.

16.2.2 **Telemedicine** is a subset of telehealth that is the delivery of clinical health care and other services, as authorized under Delaware Medicaid, by means of real-time two-way electronic interactive telecommunications system between the patient at the originating site and the health care provider is at the distant site. Two-way electronic interactive communications systems include audio, visual, or other telecommunication or electronic communication, including the application of secure video conferencing or store and forward transfer technology. Telemedicine facilitates the assessment, diagnosis, consultation, treatment, education, care management, and self-management of a patient's health.

16.2.3 The **referring provider** is the medical professional of record or medical staff person reporting to the supervising professional who has evaluated the patient, determined the need for consultation, and has arranged the services of the consulting/rendering or distant telehealth practitioner for the purpose of diagnosis and treatment.

16.2.4 The **consulting/rendering or distant telehealth practitioner** is the provider who evaluates the recipient via the telehealth mode of delivery upon recommendation of the referring provider.

16.2.5 **Originating Site** refers to where the patient is located at the time health care services are provided to the patient by means of telehealth.

An approved originating site may include the DMAP member's place of residence, day program, or alternate location in which the member is physically present, and telehealth can be effectively utilized.

16.2.6 **Distant Site** refers to the site at which a health care practitioner, legally allowed to practice in the state of Delaware or the state in which the provider is located if allowed under Delaware State law to provide telehealth services without a Delaware license through the Interstate Medical Licensure Compact or otherwise, is located while providing health care services by means of telehealth.

16.2.7 **Interactive Communication** – Telehealth delivered using multimedia communication technology that permits 2-way, real-time, interactive communications between a health care provider at a distant site and the patient at the originating site.

16.2.8 **Asynchronous or "Store-and-Forward" (S&F)** – Telehealth store-and-forward (S&F) technology is the asynchronous, secure electronic transmission of a patient's health information provided through the transference of text, digital images, sounds, previously recorded video, or responses to a survey from one location to another to allow a consulting distant telehealth practitioner the ability to obtain the information, analyze it, and report back to the referring provider.

Reimbursement for telehealth S&F services will be provided for Medicaid patients with conditions or clinical circumstances where the provision of S&F services can appropriately reduce the need for in-person visits.

16.2.9 **Remote Patient Monitoring (RPM)** – Telehealth remote patient monitoring (RPM) services use electronic information and communication technologies to collect personal health information and medical data from a patient at an originating site and share with the distant site provider. The information is transmitted synchronously or asynchronously to the distant site provider for use in treatment and management of unstable/uncontrolled medical conditions that require frequent monitoring.

The purpose of providing RPM services is to assist in the effective monitoring and management of patients whose medical needs can be appropriately and cost-effectively met through the use of RPM.
Before RPM services can be provided, the distant telehealth practitioner must ensure that:

- The recipient is cognitively and physically capable of operating the RPM equipment or that the recipient has a caregiver willing and able to assist with the equipment;
- The recipient's residence is suitable for RPM Services; and
- The recipient or caregiver, as appropriate, receives education and training on the use, maintenance, and safety of the RPM equipment.

16.3 Qualified Providers / Practitioners

16.3.1 In order to provide telehealth under DMAP, providers at both the originating and distant site must be enrolled with DMAP and must meet all requirements for their discipline as specified in the Delaware Code and the Medicaid State Plan.

16.3.2 For services delivered through telehealth technology to be covered, referring providers and distant telehealth practitioners (including out-of-region practitioners) must:

- Act within their scope of practice;
- Be licensed to provide telehealth services for which they bill DMAP in

Delaware, or the State in which the provider is located if allowed under Delaware State law to provide telehealth services without a Delaware license through the Interstate Medical Licensure Compact or otherwise;

- Be in good standing in all states in which provider is licensed;
- Not be the subject of an administrative complaint or under investigation by another state's licensing authority or board;
- Be enrolled with DMAP; and
- Have provider billing numbers (NPI and Taxonomy).

16.3.3 Distant telehealth practitioners may also need to enroll with the Department of Services for Children, Youth and their Families (DSCYF), Division of Prevention and Behavioral Health Services (DPBHS), and Division of Substance Abuse and Mental Health (DSAMH) as appropriate to provide and be reimbursed for behavioral health services.

16.3.4 The distant telehealth practitioner must be located within the continental United States. As required by §6505 of the Affordable Care Act, DMAP will not make any payments for items or services provided under the State Plan or under a waiver to any financial institution or entity located outside of the United States.

16.4 Telehealth Provider Responsibilities

16.4.1 Verify member eligibility for telehealth services.

The service must be medically necessary, written in the patient's treatment plan, and follow generally accepted standards of care.

Except for instances listed in 24 Del.C. Chapter 60, health-care providers may not deliver health-care services by telehealth and telemedicine in the absence of a health-care provider-patient relationship. A health-care provider-patient relationship may be established either in-person or through telehealth but must meet the requirements of Del.C. 24 §6003.

Consent is required to assure that the patient is a willing participant in the telehealth delivered service and to assure that the recipient retains a voice in their treatment plan.

The patient must be informed and given an opportunity to request an in-person assessment before receiving a telehealth assessment. This consent must be documented in the patient's record and must identify that the covered medical service was delivered by telehealth.

The recipient must be able to adequately communicate, either directly or through a representative, with the originating and distant site practitioners.

16.4.2 Comply with Americans with Disabilities Act (ADA) communications regulations, including language translation / interpretation accommodations.

The provision of services through telehealth must include accommodations, including interpreter and audio-visual modification, where required under the ADA, to ensure effective communication.

16.4.3 Exception for Involuntary Detention and Commitment

Where a DMAP recipient is involuntarily detained or committed to a facility for care, obtaining member consent may be impracticable. In these instances, delivery of care via telehealth should continue to meet all other telehealth policy requirements and all normal DMAP criteria for member safeguards and confidentiality. Exceptions to consent end upon the discharge of the recipient from any facility where the individual was involuntarily detained.

16.5 Operational Requirements

16.5.1 Originating Site

The originating site is represented by the patient (and referring provider, if present) in one location.

The member must be present in the Originating Site.

The referring provider is not required to be present at the originating site, but may be as medically necessary.

16.5.2 Distant Site

The distant site is represented by the consulting/rendering or distant telehealth practitioner in another location.

The distant telehealth practitioner cannot be a self-referring practitioner.

The distant site provider or other coverage must be available for appropriate follow-up care with the patient.

16.5.3 Equipment

16.5.3.1 Telehealth includes the use of numerous technologies to exchange medical information from one site to another via secure electronic communications in the form of Interactive Communication, Store-and-Forward, and Remote Patient Monitoring.

16.5.3.2 Telephones are an acceptable mode to deliver telehealth if the following conditions are met:

- It is determined that Interactive Telehealth Services are unavailable, and
- Telephonic Services are medically appropriate for the underlying covered service.

16.5.3.3 All telehealth services must comply with HIPAA patient privacy and confidentiality regulations at the site where the patient is located, the site where the distant telehealth practitioner is located, and in the transmission process.

16.5.3.4 All telehealth services must be performed on dedicated secure transmission linkages that meet the minimum federal and state requirements, including but not limited to 45 CFR, Parts 160 and 164 (HIPAA Security Rules). All confidentiality requirements that apply to written medical records will apply to services delivered by telehealth, including the actual transmission of health care data and any other electronic information and records.

16.5.3.5 Secure video-conferencing via personal computers, tablets, or other mobile devices may be considered to meet the requirements of telehealth where it can be

demonstrated that the use of the devices and the patient setting comply with this DMAP telehealth policy.

16.5.3.6 Services provided via communications equipment which do not meet this definition, are non-secure, and are non-HIPAA compliant are not covered.

16.5.3.7 All telehealth sites, both originating and distant sites, must have a written procedure detailing a contingency plan for when a failure or interoperability of the transmission or other technical difficulties render the service undeliverable. Telehealth services are not billable to DMAP or MCOs when technical difficulties preclude the delivery of part or all of the telehealth session.

16.5.4 Documentation Requirements

16.5.4.1 Originating / Referring Providers

The referring provider's medical records must document all components of the services being billed.

16.5.4.2 Distant Site

All distant telehealth practitioners are required to develop and maintain written documentation in the form of evaluations and progress notes, the same as if the documentation had originated during an in-person visit or consultation, including the mode of communication (telehealth). Distant telehealth practitioners may opt to use electronic medical records in place of paper-based written records.

16.5.5 Prescribing Medications via Telehealth

The following models may be used to prescribe medications through telehealth services.

In the absence of a proper provider-patient relationship, providers are prohibited from issuing prescriptions solely in response to an internet questionnaire, an internet consult, or a telephone consult.

16.5.5.1 First Model

The distant telehealth practitioner consults with the referring healthcare provider (if present during the telehealth session or by other means) about appropriate medications. The referring provider then executes the prescription locally for the patient.

16.5.5.2 Second Model

The distant telehealth practitioner works with a referring provider at the originating site to provide front line care, including writing prescriptions. This method is common at mental health centers. The originating site medical professional must be available on site to write the prescription exactly as described by the distant telehealth practitioner.

16.5.5.3 Third Model

The distant telehealth practitioner directly prescribes and sends/calls-in the initial prescription or refill to the patient's pharmacy.

16.5.6 Other Prescribing Guidelines for each model:

16.5.6.1 The preferred order of prescribing medications is:

1) Secure e-prescribe
2) Fax
3) Phone
4) Hard Copy – If a hard copy of a prescription is required, it can be written and sent via delivery service to the referring site for the consumer to pick-up a couple of days after the appointment; this lag can be overcome by carefully planning appointments to coincide with the refill cycle.

16.5.6.2 Procedures for Stimulants, Narcotics, and Refills:

The distant telehealth practitioner writing the prescription should be available to manage emergencies or any prescription gaps between appointments. The originating site must be able to connect with the distant telehealth practitioner outside of “telehealth transmission hours”.

16.5.6.3 Procedures for access to care between telehealth visits, including emergency and urgent care:

Patients should contact the referring provider or specialist as appropriate.

16.6 Billing

16.6.1 Prior Authorization

Prior authorization for telehealth-delivered services is not required, but the distant telehealth practitioner must obtain prior approval for any other covered services which would normally require prior authorization.

16.6.2 Reimbursement

Claims must be completed and submitted according to DMAP billing instructions.

Managed Care Organization (MCO) credentialed providers must follow the billing procedures of the MCO of record for the member.

The same procedure codes and rates apply as for services delivered in person (enrolled providers will bill Usual and Customary).

DMAP covers medically necessary telehealth services and procedures covered under the Title XIX State Plan. Qualifying practitioner services include any covered State Plan service that would typically be provided to an eligible individual in an in-person setting by an enrolled practitioner. Telehealth is not limited based on the diagnosed medical condition of the eligible recipient. All telehealth services must be furnished within the limits of provider program policies and within the scope and practice of the referring provider’s and distant telehealth practitioner’s professional standards as described and outlined in DMAP Provider Manuals.

The service provided by the consulting/rendering provider or distant telehealth practitioner must be a service covered by DMAP.

If a service is not covered in a face-to-face setting, it is not covered if provided through telehealth. A service provided through telehealth is subject to the same program restrictions, limitations, and coverage exist for the service when not provided through telehealth.

DMAP reimburses the originating site fee for telehealth services per completed transmission to licensed practitioners that are enrolled in DMAP. A facility fee for the originating site is covered, unless the originating site is the patient's home. Although a home can be considered an originating site, it is not eligible for reimbursement of the originating site fee.

Reimbursement to the referring provider will only occur when providing a separately identifiable covered service.

Reimbursement for telehealth Store-and-Forward (S&F) services will be provided for Medicaid patients with conditions or clinical circumstances where the provision of S&F services can appropriately reduce the need for in-person visits.

Services billed which indicate telehealth as the mode of service delivery but are not substantiated by either the claim form or written medical records are subject to disallowances in the course of an audit.

16.6.3 Limitations

Chart reviews, electronic mail messages, facsimile transmissions, or internet services for online medical evaluations are not considered telehealth.

Facility fees for the distant site are not covered.

DMAP will reimburse up to three (3) different consulting/distant telehealth practitioners for separately identifiable telehealth services provided to a member per date of service.

DMAP will reimburse the originating site fee for up to three (3) different originating site providers for separately identifiable telehealth services provided to a member per date of service. Each originating site provider will only be reimbursed one (1) originating site fee per member per day.

DMAP will not reimburse the referring provider at the originating site on the same date of service unless the referring provider is billing for a separate identifiable covered service. Medical records must document that all components of the service being billed were provided to the recipient.

16.6.4 Audits of Telehealth Services

16.6.4.1 Services billed which indicate telehealth as the mode of service delivery but are not substantiated by either the claim form or written medical records are subject to disallowances in the course of an audit.

16.6.5 Procedure Codes

16.6.5.1 Originating Site Providers

16.6.5.1.1 Practitioners should use HCPCS Level II procedure code Q3014 when billing for the facility fee.

16.6.5.2 Distant Site Providers

16.6.5.2.1 Practitioners should continue to bill their appropriate Usual & Customary charge for the service provided.

16.6.5.2.2 Practitioners should use 02 Modifier as Place of Service for all telehealth charges.

16.6.5.2.3 When billing the DMAP, the provider must use the appropriate CPT® procedure codes.

16.6.5.2.3.1 When billing the DMAP for S&F services, the provider must use the appropriate CPT® procedure codes under Interprofessional Telephone/Internet/Electronic Health Record Consultations.

16.6.5.2.3.2 When billing the DMAP for RPM services, the provider must use the appropriate CPT® procedure codes under Digitally Stored Data Services/Remote Physiologic Monitoring.

16.6.5.2.3.3 When billing the DMAP for Remote Physiologic Monitoring services, the provider must use the appropriate CPT® procedure codes under Remote Physiologic Monitoring Treatment Management Services.

16.6.5.2.3.4 When billing the DMAP for telephonic services that have been determined to be an acceptable mode to deliver telehealth, per 16.5.3, but that do not meet the full requirements of an E/M CPT® code, the provider must use the appropriate CPT® procedure codes under Telephone Services (Non-Face-to-Face Services) or Telephone Services (Non-Face-to-Face Nonphysician Services).

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17.0 Specific Criteria for Annual Behavioral Health Well Check

17.1 Overview

Beginning January 1, 2024, all insurance companies must provide access to an "annual behavioral health well check" in compliance with 24 Del Admin. Code Title 31 Chapter 5 §531. The goal of annual behavioral health well check is to promote health and foster the coordination of screening and preventive mental health services.

17.2 Definitions

17.2.1 An **annual behavioral health well check** is an annual visit with a licensed mental health clinician who has at minimum a master's level degree. The well check must include, but is not limited to, a review of medical history, evaluation of adverse childhood experiences, use of a group of developmentally appropriate mental health screening tools, and may include anticipatory behavioral health guidance congruent with stage of life.

17.3 Member Eligibility

17.3.1 All DMAP members are eligible to receive an annual behavioral health well check.

17.3.2 Providers are required to verify member eligibility, managed care enrollment, and other important member information prior to rendering services by accessing one of the EVS options. Instructions for accessing EVS are described in the in the EVS section of the DMAP General Billing Manual.

17.4 Qualified Providers / Practitioners

17.4.1 The annual behavioral health well check must be performed by a licensed mental health clinician with a minimum of a master's level degree.

17.4.2 The licensed mental health clinician must be currently enrolled as a provider with DMAP.

17.5 Billing Procedures

17.5.1 Billing Requirements

17.5.1.1 When billing for an annual behavioral health well check, providers must use the diagnosis of "annual behavioral health well check."

17.5.1.2 Providers must use the following codes when billing DMAP:

Code	Description
99429-HE	Annual Behavioral Health Well Check

17.5.1.3 The annual behavioral health well check must be billed with modifier "HE" (Mental Health Program) to document that the service was performed.

17.5.1.4 Code 99429-HE must not be billed within 12 months of a previous billing of 99429-HE for the same beneficiary.

17.5.1.5 Billing of code 99429-HE more than once within 12 months of a previous billing of 99429-HE will result in a denial of the later 99429-HE.

18.0 Treatment of Gender Dysphoria Disorder

18.1 Introduction

Services for the treatment of Gender Dysphoria Disorder are provided in accordance with the Delaware State Plan.

18.2 Definitions

As used in this policy, the following definitions are provided:

- **Gender Dysphoria (Gender Identity Disorder):** Discomfort or distress related to incongruence between a person's gender identity, sex assigned at birth, and/or primary or secondary sex characteristics.
- **Gender Dysphoria:** Distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics).
- **Gender Identity:** A person's intrinsic sense of being male (a boy or a man), female (a girl or woman), or an alternative gender (e.g., boygirl, girlboy, transgender, genderqueer, eunuch).
- **Gender Identity Disorder:** Formal diagnosis set forth by the Diagnostic Statistical Manual of Mental Disorders, 4th Edition, Text Rev (DSM IV-TR) (American Psychiatric Association, 2000). Gender identity disorder is characterized by a strong and persistent cross-gender identification and a persistent discomfort with one's sex or sense of inappropriateness in the gender role of that sex, causing clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- **Gender Nonconforming (GNC):** An adjective used as an umbrella term to describe people whose gender expression or gender identity differs from gender norms associated with their assigned birth sex.
- **Gender Reassignment Surgery (GRS) (gender affirmation surgery or sex reassignment surgery):** Surgery to change primary and/or secondary sex characteristics to better align a person's physical appearance with their gender identity. Sex reassignment surgery can be an important part of medically necessary treatment to alleviate gender dysphoria and may include mastectomy, hysterectomy, metoidioplasty, phalloplasty, breast augmentation, penectomy, orchiectomy, vaginoplasty, facial feminization surgery, and/or other surgical procedures.
- **Hormone Therapy (gender affirming hormone therapy, hormone replacement therapy):** The use of hormones to masculinize or feminize a person's body to better align that person's physical characteristics with their gender identity. People wishing to feminize their body receive antiandrogens and/or estrogens; people wishing to masculinize their body receive testosterone. Hormone therapy may be an important part of medically necessary treatment to alleviate gender dysphoria.
- **Informed Consent of partially or fully irreversible treatment for Gender Dysphoria:** An agreement, in writing, given to a provider by a person receiving treatment for gender dysphoria, acknowledging that they have been informed of and understand all of the psychological and physical benefits, limitations, and risks of said treatment, as well as its psychosocial implications, relevant to the patient's age, previous experience, and concurrent physical or mental

health concerns. Informed consent should be documented in the medical record.

- **Puberty Suppression (puberty blocking, puberty delaying therapy):** A treatment that can be used to temporarily suppress the development of secondary sex characteristics that occur during puberty in youth, typically using gonadotropin-releasing hormone (GnRH) analogues. Puberty suppression may be an important part of medically necessary treatment to alleviate gender dysphoria. Puberty suppression can provide adolescents time to determine whether they desire further transitional interventions for gender dysphoria, and can additionally serve a diagnostic role to help determine if further medical intervention is warranted.

18.3 Indications for Coverage

Services are covered as needed based upon medical necessity.

18.4 Covered Services

18.4.1 Psychotherapy for gender dysphoria and associated co-morbid psychiatric diagnoses. (Most commonly mood disorders, anxiety disorders, and developmental personality issues.) The benefits are the same as any other outpatient mental health service.

18.4.2 Continuous Hormone Therapy

18.4.2.1 The benefits are the same as any other eligible medication within the prescribed treatment period.

18.4.3 Laboratory testing to monitor continuous hormone therapy is the same as any other outpatient diagnostic service within the prescribed treatment protocol.

18.4.4 Gender Reassignment Surgery (GRS)

18.4.5 Puberty Suppression Therapy (puberty blocking, puberty delaying therapy) when determined to be medically necessary for treatment of gender dysphoria in adolescents.

18.5 Puberty Suppression Therapy for Adolescents Eligibility Qualifications

The Adolescent DMAP member must meet all of the following eligibility qualifications for puberty suppression therapy:

18.5.1 The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed);

18.5.2 Gender dysphoria emerged or intensified with the onset of puberty;

18.5.3 Any transitional or co-existing psychological, medical, socio-cultural, or family problems (including potential harassment or bullying) that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment;

18.5.4 The adolescent will have continuing access to medical and mental health evaluation, support, and psychotherapy, preferably by a collaborative team, to include a family therapy/support component as indicated;

18.5.5 The adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parent(s) or other caretaker(s) or guardian(s) has/have consented to the treatment and are involved in supporting the adolescent throughout the treatment process; and

18.5.6 The adolescent must be referred for Puberty Suppression Therapy by a DMAP enrolled licensed mental health professional qualified in the treatment of gender dysphoric and transgendered individuals.

18.5.7 Prior authorization is required prior to prescribing a puberty suppressant to an adolescent. The following forms must be submitted with the prior authorization request, on the secure provider portal. All Gender Dysphoria forms can be found on the DMAP Provider Portal.

18.5.7.1 The Puberty Suppression for Adolescents Referral Form for Mental Health Professionals, and

18.5.7.2 The completed Informed Consent Form for Puberty Suppression for Adolescents with Gender Identity Disorder.

18.6 Hormone Replacement Eligibility Qualifications

The DMAP member must meet all of the following eligibility qualifications for hormone replacement:

18.6.1 The DMAP member must be diagnosed with gender dysphoria;

18.6.1.1 The initial evaluation must be performed by, or in consultation with, a DMAP enrolled licensed mental health professional qualified in the treatment of gender dysphoric and transgendered individuals.

18.6.2 Initial hormone therapy must be preceded by:

18.6.2.1 A documented real-life experience (living as the other gender) of at least three months prior to the administration of hormones (This documented real-life experience may substitute for the minimum psychotherapy requirement only upon certification by a qualified mental health professional experienced in the treatment of gender dysphoric and transgendered individuals); and

18.6.2.2 A thorough evaluation by a DMAP enrolled qualified mental health professional* followed by a period of psychotherapy of a duration specified by a DMAP enrolled qualified mental health professional* (Minimum of three months, though longer periods may be recommended. Psychotherapy may run concurrently with 18.6.2.3 below); and

18.6.2.3 Informed consent for hormone therapy.

18.6.3 The DMAP member must be referred for Hormone Replacement Therapy by a DMAP enrolled licensed mental health professional qualified in the treatment of gender dysphoric and transgendered individuals.

18.6.4 Prior authorization is required prior to prescribing Hormone Replacement Therapy medications for Gender Dysphoria. The following forms must be submitted with the prior authorization request, on the secure provider portal. All Gender Dysphoria forms can be found on the DMAP Provider Portal.

18.6.4.1 The Hormone Replacement Therapy Referral Form for Mental Health Professionals, and

18.6.4.2 The completed Informed Consent Form for Feminizing/Masculinizing Hormone Replacement Therapy.

18.7 Gender Reassignment Surgery Eligibility Qualifications

The DMAP member must meet all of the following eligibility qualifications for gender reassignment surgery:

18.7.1 The DMAP member must meet the Hormone Replacement Therapy Eligibility Qualifications listed in the previous section;

18.7.2 The surgery must be performed by a DMAP enrolled qualified professional provider at a facility with a history of treating individuals with gender identity disorder;

18.7.3 Informed consent for gender reassignment surgery must be provided;

18.7.4 A treatment plan must be in place and must conform to the World Professional Association for Transgender Health (WPATH) Standards of Care (SOC) (WPATH 7th edition);

18.7.4.1 The DMAP member must be in compliance with their treatment plan. This includes any additional pre-surgical requirements identified by the person's provider(s) and documented in the treatment plan.

18.7.5 Prior to the surgery, the DMAP member must complete twelve (12) months of successful continuous full-time real life experience in the desired gender, as confirmed by a medical or mental health professional experienced in gender reassignment surgery;

18.7.6 Continuing postoperative follow-up by the surgeon and mental health professional must be arranged in advance of the surgery and documented in the Treatment Plan; and

18.7.7 Referrals to support groups and resources specific to transgender issues should be arranged in advance of the surgery;

18.7.8 The DMAP member must be age eighteen (18) years or older for irreversible surgical interventions; and

18.7.8.1 A DMAP member under the age of eighteen (18), but no less than the age of sixteen (16), may be assessed for irreversible surgical interventions when the following conditions are met, in addition to the other eligibility qualifications listed in this section:

18.7.8.1.1 The DMAP member must first meet all of the Puberty Suppression Therapy for Adolescents Eligibility Qualifications and Hormone Replacement Qualifications listed above;

18.7.8.1.2 The DMAP member exhibits the capacity to make a fully informed decision and to consent for treatment;

18.7.8.1.3 Informed consent has been obtained by:

- A parent or guardian of any minor,
- A married minor for himself or herself,
- An emancipated minor for himself or herself, or
- A relative caregiver acting pursuant to an Affidavit of Establishment of Power to Relative Caregivers to Consent to Medical Treatment of Minors.

18.7.8.1.4 The DMAP member's treatment plan must be monitored regularly by a DMAP enrolled qualified mental health professional and the DMAP member's pediatrician or general practitioner before, during, and after reassignment;

18.7.8.1.5 The DMAP member's treatment plan must include documentation that:

- Extensive exploration of psychological, family, and social issues, as outlined in the WPATH Standards of Care, has occurred;
- All available, and applicable, physical interventions, ranging from fully reversible to irreversible, have been addressed in the context of adolescent development and have followed a staged process; and
- The DMAP member has had adequate time to assimilate to the effects of earlier interventions.

18.7.9 The DMAP member must be referred by a DMAP enrolled licensed mental health professional qualified in the treatment of gender dysphoric and transgendered individuals for chest/breast Gender Reassignment Surgery; or

18.7.10 The DMAP member must be referred by two (2) DMAP enrolled licensed mental health professionals qualified in the treatment of gender dysphoric and transgendered individuals for genital Gender Reassignment Surgery.

18.7.11 Prior authorization is required prior to performing gender reassignment surgery for Gender Dysphoria. The following forms must be submitted with the prior authorization request, on the secure provider portal. All Gender Dysphoria forms can be found on the DMAP Provider Portal.

18.7.11.1 The Gender Reassignment Surgery Referral Form for Mental Health Professionals (one (1) for chest/breast Gender Reassignment Surgery and two (2) for genital Gender Reassignment Surgery, and

18.7.11.2 The completed Informed Consent Form for Female to Male/Male to Female Gender Reassignment Surgery.

18.8 Exclusions

The following services are not covered:

18.8.1 Treatment received outside of the United States.

18.8.2 Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics.

18.8.3 Sperm preservation in advance of hormone treatment or gender surgery.

18.8.4 Cryopreservation of fertilized embryos.

18.8.5 Suction-assisted lipoplasty of the waist.

18.8.6 Surgical treatment not prior authorized by the insurer.

18.8.7 Drugs for sexual performance for patients that have undergone genital reconstruction.

18.8.8 Drugs for cosmetic purposes.

18.8.9 Hormone therapy except as described in the Covered Services section above.

18.8.10 Transportation, meals, lodging or similar expenses except as defined in DMAP Policy Manuals.

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HCPCS Procedure Codes

19.0 Appendix D - HCPCS Procedure Codes

Effective for dates of service on and after 7/1/02, it is the responsibility of the provider to bill the DMAP using appropriate CPT®/HCPCS procedure codes.

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Over-the-Counter Products

20.0 Appendix E - Over-the-Counter Products

The following is the list of OTC products that will be covered:

Categories	Inclusion	Exclusion
Analgesic oral or rectal	Acetaminophen/combinations	
	Non-steroidal anti-inflammatory	
	Salicylates	
Heartburn	Acid reducers	
	Antacids	
Antiflatulents	Simethicone/combination	
Antidiarrheal	Bismuth subsalicylate	
	Kaolin-pectin combination	
	Loperamide	
Antinauseants	Dimenhydrinate	
	Meclizine hydrochloride	
	Phosphorated carbohydrate solution	
Cough & cold, oral*subject to PDL	Antihistamines	Mouthwashes
	Antitussives	Throat sprays
	Decongestants	Lozenges
	Expectorants	Troches
Cough & cold, topical		Rubs
Contraceptives		Condoms
Diabetic supplies* subject to PDL	Insulin	
	Diagnostic strips	
	Lancets	
	Monitoring devices	
Hematinics		Long acting products
Laxative & stool softeners		
Topical Antiparasitics	Diethyltoluamide	
	Piperonyl butoxide	
	Permenthrin	
	Pyrethrins	
	Picaridin	
Nasal preparations	Cromolyn	Nasal decongestant inhalers
	Ephedrine	
	Epinephrine	
	Naphzoline	
	Oxymetazoline	
	Phenylephrine	
	Sodium chloride	
	Xylometazoline	

Categories	Inclusion	Exclusion
Opthalmic preparations	Allergy eye preparations	
	Ocular lubricants	
	Phenylephrine	
	Sodium chloride	
Topical anesthetics	Benzocaine	
	Capsaicin	
	Dibucaine	
	Lidocaine	
	Pramoxine	
Topical antibacterials	Bacitracin	
	Chlorhexidine gluconate	
	Neomycin	
	Polymycin	
	Providone-iodine	
	Tetracycline	
Topical/vaginal fungicidals	Iodochlorhydroxyquin (clioquinol)	
	Miconazole nitrate	
Topical/vaginal fungicidals	Clotrimazole	
	Tolnaftate	
	Triacetin	
	Undecylenic acid, ester, salts	
Vitamins & mineral	Single entity vitamins	Electrolytes
	Multiple vitamins w/minerals	
	Nicotinic acid	
	Calcium salts	
	Dialysis replacement products	
Miscellaneous	Colloidal oatmeal baths	
Digestive enzymes	Pancrelipase	
	Tar preparations	Tar, soaps or cleansing agents

Consent Form

21.0 Appendix F - Consent Form

DELAWARE MEDICAL ASSISTANCE PROGRAM
CONSENT FORM

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from _____ (Doctor or Clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or Medcaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED **PERMANENT** AND **NOT REVERSIBLE**. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a _____. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least thirty days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on _____ (Month Day Year)

I, _____, hereby consent of my own free will to be sterilized by _____ (Doctor) by a method called _____. My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health, Education and Welfare or

Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form.

_____ (Signature) Date: _____ (Month Day Year)

You are requested to supply the following information, but it is not required:

Race and ethnicity designation (Please Check)

[ ] American Indian or Alaska Native
[ ] Asian or Pacific Islander
[ ] Black (not of Hispanic origin)
[ ] Hispanic
[ ] White (not of Hispanic origin)

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

_____ (Interpreter) _____ (Date)

DOC. NO. 35-07-01-89-08-02-ES-14

STATEMENT OF PERSON OBTAINING CONSENT

Before _____ (Name of Individual) signed the consent form, I explained to him/her the nature of the sterilization operation _____, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal Funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure.

_____ (Signature of Person Obtaining Consent) _____ (Date)

_____ (Facility)

_____ (Address)

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon _____ (Name of Individual to be Sterilized) on _____ (Date of Sterilization) _____ (Operation) I explained to him/her the nature of the sterilization operation _____ (Specify Type of Operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequences of the procedure.

(Instructions for use of alternative final paragraphs: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least thirty days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested):

[ ] Premature delivery
[ ] Individual's expected date of delivery:
[ ] Emergency abdominal surgery:

(describe circumstances):

_____ (Physician) _____ (Date)

Awareness Form

22.0 Appendix G - Awareness Form

441.255 Sterilization by hysterectomy

(a) FFP is not available in expenditures for a hysterectomy if --

(1) It was performed solely for the purpose of rendering an individual permanently incapable of reproducing, or

(2) If there was more than one purpose to the procedure, it would not have been performed but for the purpose of rendering the individual permanently incapable of reproducing

(b) FFP is available in expenditure for a hysterectomy not covered by paragraph (a) of this section if –

(1) The person who secured authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing that the hysterectomy will render the individual permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed wither a written acknowledgement of receipt of that information.
441.256

Patient's Name: _____

Medicaid No._____Date of Surgery_____

Physician's Name: _____

Surgical Procedure: _____

****

Section A: Complete this section for patient's apparently presently capable of reproducing:

1. **Patient acknowledgement:**
   It has been explained to me that the surgical procedure to be performed is medically necessary and as a result will render me permanently incapable of reproducing.

Date: _____ _____
Patient's Signature (or Patient's Representative)

Date: _____ _____
Interpreter's Signature

2. **Physician Certification:**
   The surgical procedure to be performed on_____is medically
   Patient's Name
   indicated and is not solely for the purpose of rendering her permanently incapable of reproducing.

Date:_____Physician's Signature: _____

****

Section B: Complete this section for other patients:

_____ This patient was surgically sterilized on _____
Approximate date

_____ This patient is post-menopausal.

_____ The individual requires a hysterectomy because of a life-threatening emergency situation. Include a description of the nature of the emergency:

_____

_____

_____

_____

Date:_____Physician's Signature: _____

23.0 Appendix H - Reserved

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	Reserved for Future Use

24.0 Appendix I - Reserved

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Provider Performed Microscopy Procedures

25.0 Appendix J - CLIA Certificate for Provider-Performed Microscopy Procedures (PPMP)

25.1 Covered Procedures

Code	Description
81000	Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy
81001	Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy (NOTE: May only be used when the lab is using an automated dipstick urinalysis instrument approved as waived.)
81015	Urinalysis; microscopic only
81020	Urinalysis; two or three glass test
89190	Nasal smear for eosinophils
G0026	Fecal leukocyte examination

25.2 Non-Covered Procedures

NOTE: The DMAP considers the following provider-performed microscopy procedures to be part of the physician evaluation and management service. Therefore, the following are not separately reimbursable by DMAP:

Code	Description
Q0111	Wet mounts, including preparations of vaginal, cervical or skin specimen
Q0112	All potassium hydroxide (KOH) preparations
Q0113	Pinworm examinations

NOTE: The DMAP does not cover any services relating solely to the treatment of infertility. Therefore, the following provider-performed microscopy procedures are not reimbursable by DMAP:

Code	Description
Q0114	Fern test
Q0115	Post-coital direct, qualitative examinations of vaginal or cervical mucous
G0027	Semen analysis; presence and/or motility of sperm excluding Huhner test

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26.0 Appendix K - Reserved

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Specific Laboratory Billing Instructions

27.0 Appendix L - Specific Laboratory Billing Instructions

27.1 Multiple Units of Service

The following restrictions apply when billing for multiple units of service:

Repetition of the same test on the same specimen must not be billed.

When the same test is performed on separate specimens collected on the same day from the same patient, bill for the second test with a modifier of “91” defined as “repeat clinical diagnostic laboratory test”.

When different procedures are described by one HCPCS procedure code, bill for multiple units of service. In the comment section of the 837 Professional claim (Loop 2300-Claim Information in the NTE segment), identify the procedures performed.

EXAMPLE: When both a wound culture and an eye culture are performed on the same day, bill for two units of the appropriate code. In the comment section of the 837 Professional claim, state that one wound culture and one eye culture were performed.

27.2 Pregnancy Tests

The following restrictions apply:

HCPCS procedure code 81025 (Urine pregnancy test, by visual color comparison methods) should be used for pregnancy tests performed on urine samples that are reported as positive or negative by a visual color comparison.

HCPCS procedure code 84703 [Gonadotropin, chorionic (hCG); qualitative] should be used for pregnancy tests reported as positive or negative.

HCPCS procedure code 84702 [Gonadotropin, chorionic (hCG); quantitative) should be used when determining the range of values of the beta sub-unit of the chorionic gonadotropin. DO NOT USE THIS CODE FOR ROUTINE PREGNANCY TESTS.

27.3 Organ or Disease Oriented Panels

Panels are groups of laboratory tests that are performed and billed as a single unit. Practitioners must use the appropriate single procedure code that describes the group of tests being performed.

The CPT® codes for Organ or Disease Oriented Panels will be used for dates of service 7/1/02 and after.

When reporting any of these 22 tests, regardless of whether the tests are performed using manual or semi-automated methods, or on automated multichannel equipment, use the appropriate profile code 80002 - G0060 listed below:

Code	Description
80002	Automated multichannel test; 1 or 2 clinical chemistry tests
80003	Automated multichannel test; 3 clinical chemistry tests

80004	Automated multichannel test; 4 clinical chemistry tests
80005	Automated multichannel test; 5 clinical chemistry tests
80006	Automated multichannel test; 6 clinical chemistry tests
80007	Automated multichannel test; 7 clinical chemistry tests
80008	Automated multichannel test; 8 clinical chemistry tests
80009	Automated multichannel test; 9 clinical chemistry tests
80010	Automated multichannel test; 10 clinical chemistry tests
80011	Automated multichannel test; 11 clinical chemistry tests
80012	Automated multichannel test; 12 clinical chemistry tests
80016	Automated multichannel test; 13 - 16 clinical chemistry tests
80018	Automated multichannel test; 17 - 18 clinical chemistry tests
80019	Automated multichannel test; 19 clinical chemistry tests
G0058	Automated multichannel test; 20 clinical chemistry tests
G0059	Automated multichannel test; 21 clinical chemistry tests
G0060	Automated multichannel test; 22 clinical chemistry tests

EXAMPLE: If a BUN and a glucose were run on the same specimen, the correct code would be one unit of 80002. If only a glucose was ordered, the correct code would still be one unit of 80002. If a glucose was run a 9 AM and again at 2 PM on the same day on different specimens, two units of 80002 would be billable.

EXAMPLE: If five of the above tests are ordered, the correct code would be one unit of 80005. Fifteen tests would be billed as one unit of 80016 while twenty-one tests would be one unit of G0059. In each case, the unit of service would be one, not the number of tests actually performed.

27.4 Drug Testing (Presumptive and Definitive)

Refer to Current Procedural Terminology (CPT®) Manual or Healthcare Common Procedure Coding System (HCPCS) for correct codes as published by American Medical Association (AMA).

Choose the code based on medical necessity. The services should be reasonable and necessary.

27.5 Therapeutic Drug Assays

Use the specific procedure code listed in the CPT® book for individual quantitative assay.

Refer to Current Procedural Terminology (CPT®) Manual for correct codes as published by American Medical Association (AMA).

Choose the code based on medical necessity. The services should be reasonable and necessary.

27.6 Urinalysis

Refer to Current Procedural Terminology (CPT®) Manual or Healthcare Common Procedure Coding System (HCPCS) for correct codes as published by American Medical Association (AMA).

Choose the code based on medical necessity. The services should be reasonable and necessary.

27.7 Chemistry

Refer to Current Procedural Terminology (CPT®) Manual for correct codes as published by

American Medical Association (AMA).

Choose the code based on medical necessity. The services should be reasonable and necessary.

27.8 Hematology (85000 - 85999)

When billing codes for a complete blood count (CBC) or hemogram, identified as HCPCS procedure codes 85021, 85022, 85023, 85024, 85025, 85027, or 85031, do not bill for any code that is a component of a CBC for the same specimen. The following are the HCPCS procedure codes for components: 85007, 85008, 85013, 85014, 85018, 85041, 85048, 85585, 85590, and 85595.

Providers are reminded not to use multiple procedure codes when a single procedure code accurately describes the service rendered.

27.9 Immunology (86000 - 86999)

When there is no specific code for an immunology procedure, the code for the methodology is to be used. Certain codes can be used to describe many different tests. When two or more different tests are described by the same code and are performed on the same patient on the same day, bill on a single line using multiple units of service. In the comment section of the 837 Professional claim, identify the procedures performed.

27.10 Microbiology (87001 - 87999)

The following policies apply:

A screening culture is one in which a single pathogen is isolated but may or may not be definitively identified (CPT® codes 87081 or 87084).

EXAMPLE: When a throat culture is screened for the presence or absence of group A beta streptococci using a low concentration bacitracin disc, bill for one unit of 87081. Identification aids such as bacitracin and neomycin discs are considered part of the screen and should not be billed in addition to the 87081.

Presumptive identification of microorganisms is defined as identification by colony morphology, growth on selective media, Gram stains, or up to three tests (e.g., catalase, oxidase, indole, urase). Presumptive codes include: 87040, 87045, 87046, 87070, 87071, 87073, 87075, 87076 or 87088.

Definitive identification of microorganisms is defined as an identification to the genus or species level that requires additional tests (e.g., biochemical panels, slide cultures). Codes 87076 and 87077 may be used in addition to the above presumptive codes, when additional testing has been performed.

If additional studies involve molecular probes, chromatography, or immunologic techniques, these should be separately coded in addition to definitive identification codes (CPT® codes 87140, 87143, 87147, 87149, 87152, and 87158).

Direct sensitivities are not reimbursable. A direct sensitivity is inoculated directly from the specimen at the time of the initial culture. DO NOT use HCPCS procedure codes 87181, 87184-87188, or 87190 to describe direct sensitivities. Sensitivities will only be reimbursed after a pathogen has been isolated and set up for sensitivities.

When performing chlamydia and GC by DNA Probe, bill for one unit of 87490 (Chlamydia trachomatis, direct probe technique) and one unit of 87590 (Neisseria gonorrhoeae, direct probe technique).

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Abortion Justification Form

28.0 Appendix M - Abortion Justification Form

Federal law has enacted new Hyde Amendment requirements for Federally funded abortions. One of those requirements is that, in order for Medicaid to reimburse for an abortion, a physician must certify that a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused or arising from the pregnancy itself, that would place the woman in danger of death unless an abortion is performed. Previously, a physician was required to certify only that, in the physician's professional judgment, the life of the woman would be endangered if the fetus were carried to term.

The physician must complete this form and attach it to the claim being submitted for payment.

Member's Name:_____

Address:_____

_____

Phone #:_____Medicaid ID#:_____

Primary Diagnosis for Abortion:_____

Other Diagnoses:_____

STATEMENT OF JUSTIFICATION: The physician must detail the medical justification for the abortion and attach any pertinent information including laboratory tests, radiological evaluations, consultations, etc. If more space is needed additional pages may be attached.

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

I,_____, certify the above statement to be true and accurate. (Physician's Live Signature)

Printed Name of Physician:_____

Physician's Address:_____

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Reserved for Future Use

29.0 Appendix N - Reserved

Periodicity Schedule

30.0 Appendix O - Periodicity Schedule

NOTE: The number of visits for infants through 20 years of age listed in the General Limitation column is from the EPSDT Periodicity Schedule developed by the Division of Public Health for use in providing EPSDT services both in fee for service and MCO delivery systems. DMAP policy follows Bright Futures/American Academy of Pediatrics Recommendations for Preventive Pediatric Health Care Periodicity Schedule.

30.1 Periodic Evaluation and Management of a Healthy Individual

Code	Description	General Limitation	Exceptions
99381 99391	Infant (age under 1 year)	9 visits before first birthday	
99382 99392	Early childhood (ages 1 through 4 years)	4 visits between the first and second birthdays OR 3 visits between the second and third birthdays OR 1 visit/calendar year for ages 3 and 4	Child in the process of enrolling in a Headstart Program – periodic evaluation required within the six months preceding date of Headstart enrollment. In the comment section of the claim form, note that “periodic evaluation was necessary for Headstart enrollment” and provide the expected Headstart enrollment date.
99383 99393	Late childhood (ages 5 through 11 years)	1 visit/calendar year	
99384 99394	Adolescent (ages 12 through 17 years)	1 visit/calendar year	

Code	Description	General Limitation	Exceptions
99385 99395	Ages 18 - 39 years	1 visit/calendar year for ages 18 through 20 OR 1 visit every 3 calendar years for ages 21 through 39	Medicaid approves a yearly interval history and examination if member is: In a long term care facility (SNF, ICF, ICF/MR, ICF/MR group home, or ICF/IMD) OR In a Home and Community-Based Waiver OR A member of Community Support Services for mental health or substance abuse In the comment section of the claim form, note the program under which the member is covered and the facility/residence name if other than their own home.
99386 99396	Ages 40 – 64 years	1 visit every 3 calendar years for ages 40 through 49 OR 1 visit every 2 calendar years for ages 50 through 59 OR 1 visit/calendar year for ages 60 through 64	See 99385 and 99395
99387 99397	Ages 65 years and over	1 visit every calendar year for ages 66 and over	See 99385 and 99395

30.2 Routine Gynecological Evaluation

Use the following procedure codes for routine gynecological evaluation.

Code	Description
S0610	Annual gynecological examination; new patient
S0612	Annual gynecological examination; established patient

NOTE: Use modifier “FP” with the appropriate code when examination includes family planning. Only one routine gynecological evaluation can be paid per calendar year regardless of provider.

Medicare Coverage Issues Manual Section 50-36

31.0 Appendix P - 50-36 Positron Emission Tomography (PET) Scans

COVERAGE ISSUES - DIAGNOSTIC SERVICES 06-03

50-36 POSITRON EMISSION TOMOGRAPHY (PET) SCANS

I. General Description

Positron emission tomography (PET) is a noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the [human] body. A positron camera (tomograph) is used to produce cross-sectional tomographic images, which are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as Fluoro-D-Glucose (FDG), that are administered intravenously to the patient.

The following indications may be covered for PET under certain circumstances. Details of Medicare PET coverage are discussed later in this section. Unless otherwise indicated, the clinical conditions below are covered when PET utilizes FDG as a tracer.

NOTE: This manual section lists all Medicare-covered uses of PET scans. A particular use of PET scans is not covered unless this manual specifically provides that such use is covered. Although this section lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all non-covered uses.

Clinical Condition	Effective Date	Coverage
Solitary Pulmonary Nodules (SPNs)	January 1, 1998	Characterization
Lung Cancer (Non Small Cell)	January 1, 1998	Initial staging
Lung Cancer (Non Small Cell)	July 1, 2001	Diagnosis, staging and restaging
Esophageal Cancer	July 1, 2001	Diagnosis, staging and restaging
Colorectal Cancer	July 1, 1999	Determining location of tumors if rising CEA level suggests recurrence
Colorectal Cancer	July 1, 2001	Diagnosis, staging and restaging
Lymphoma	July 1, 1999	Staging and restaging only when used as an alternative to Gallium scan
Lymphoma	July 1, 2001	Diagnosis, staging and restaging
Melanoma	July 1, 1999	Evaluating recurrence prior to surgery as an alternative to a Gallium scan
Melanoma	July 1, 2001	Diagnosis, staging and restaging; Non-covered for evaluating regional nodes
Breast Cancer	October 1, 2002	As an adjunct to standard imaging modalities for staging patients with distant metastasis or restaging patients with locoregional recurrence or metastasis; as an adjunct to standard imaging modalities for monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is

Clinical Condition	Effective Date	Coverage
		anticipated
Head and Neck Cancers (excluding CNS and thyroid)	July 1, 2001	Diagnosis, staging and restaging
Thyroid Cancer	October 1, 2003	Restaging of recurrent or residual thyroid cancers of follicular cell origin that have been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and negative I-131 whole body scan performed
Myocardial Viability	July 1, 2001 to Sept. 30, 2002	Covered only following inconclusive SPECT
Myocardial Viability	October 1, 2002	Primary or initial diagnosis, or following an inconclusive SPECT prior to revascularization. SPECT may not be used following an inconclusive PET scan
Refractory Seizures	July 1, 2001	Covered for pre-surgical evaluation only
Perfusion of the heart using Rubidium 82* tracer	March 14, 1995	Covered for noninvasive imaging of the perfusion of the heart
Perfusion of the heart using ammonia N-13* tracer	October 1, 2003	Covered for noninvasive imaging of the perfusion of the heart

*Not FDG-PET.

II. General Conditions of Coverage for FDG PET

A. Allowable FDG PET Systems

1. Definitions: For purposes of this section:
   a. "Any FDA approved" means all systems approved or cleared for marketing by the FDA to image radionuclides in the body.
   b. "FDA approved" means that the system indicated has been approved or cleared for marketing by the FDA to image radionuclides in the body.
   c. "Certain coincidence systems" refers to the systems that have all the following features:
   Crystal at least 5/8-inch thick;
   Techniques to minimize or correct for scatter and/or randoms; and
   Digital detectors and iterative reconstruction.

Scans performed with gamma camera PET systems with crystals thinner than 5/8-inch will not be covered by Medicare. In addition, scans performed with systems with crystals greater than or equal to 5/8-inch in thickness, but that do not meet the other listed design characteristics are not covered by Medicare.

2. Allowable PET systems by covered clinical indication:

Allowable Type of FDG PET System	
Covered Clinical Condition	**On or after January 1, 2002**
Characterization of single pulmonary nodules	FDA approved: Full ring Partial ring Certain coincidence systems
Initial staging of lung cancer (non small cell)	FDA approved: Full ring Partial ring Certain coincidence systems
Determining location of colorectal tumors if rising CEA level suggests recurrence	FDA approved: Full ring Partial ring Certain coincidence systems
Staging or restaging of lymphoma only when used as an alternative to a gallium scan	FDA approved: Full ring Partial ring Certain coincidence systems
Evaluating recurrence of melanoma prior to surgery as an alternative to a gallium scan	FDA approved: Full ring Partial ring Certain coincidence systems
Diagnosis, staging, and restaging of colorectal cancer	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of esophageal cancer	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of head and neck cancers (excluding CNS and thyroid)	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of lung cancer (non small cell)	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of lymphoma	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of melanoma (noncovered for evaluating regional nodes)	FDA approved: Full ring Partial ring
Determination of myocardial viability only following an inconclusive SPECT	FDA approved: Full ring Partial ring
Presurgical evaluation of refractory seizures	FDA approved: Full ring
Breast Cancer	Effective October 1, 2002, full and partial ring
Thyroid Cancer	Effective October 1, 2003, full and partial ring
Myocardial Viability Primary or initial diagnosis prior to revascularization	Effective October 1, 2002, full and partial ring

B. Regardless of any other terms or conditions, all uses of FDG PET scans, in order to be covered by the Medicare program, must meet the following general conditions prior to June 30, 2001:

1. Submission of claims for payment must include any information Medicare requires to assure that the PET scans performed were: (a) medically necessary, (b) did not unnecessarily duplicate other covered diagnostic tests, and (c) did not involve investigational drugs or procedures using investigational drugs, as determined by the Food and Drug Administration (FDA).

2. The PET scan entity submitting claims for payment must keep such patient records as Medicare requires on file for each patient for whom a PET scan claim is made.

C. Regardless of any other terms or conditions, all uses of FDG PET scans, in order to be covered by the Medicare program, must meet the following general conditions as of July 1,2001:

1. The provider of the PET scan should maintain on file the doctor's referral and documentation that the procedure involved only FDA approved drugs and devices, as is normal business practice.

2. The ordering physician is responsible for documenting the medical necessity of the study and that it meets the conditions specified in the instructions. The physician should have documentation in the beneficiary's medical record to support the referral to the PET scan provider.

3.

III. Covered Indications for PET Scans and Limitations/Requirements for Usage

For all uses of PET relating to malignancies the following conditions apply:

1. Diagnosis: PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare. PET is not covered for other diagnostic uses, and is not covered for screening (testing of patients without specific signs and symptoms of disease).

2. Staging and or Restaging: PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

3. Monitoring: Use of PET to monitor tumor response during the planned course of therapy (i.e., when no change in therapy is being contemplated) is not covered except for breast cancer. Restaging only occurs after a course of treatment is completed, and this is covered, subject to the conditions above.

NOTE: In the absence of national frequency limitations, contractors, should, if necessary, develop frequency requirements on any or all of the indications covered on and after July 1, 2001.

IV. Coverage of PET for Perfusion of the Heart

A. Rubidium 82

Effective for services performed on or after March 14, 1995, PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Rubidium 82 (Rb 82) are covered, provided the requirements below are met.

Requirements:

The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or

The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)

For any PET scan for which Medicare payment is claimed for dates of services prior to July 1, 2001, the claimant must submit additional specified information on the claim form (including proper codes and/or modifiers), to indicate the results of the PET scan. The claimant must also include information on whether the PET scan was done after an inconclusive noninvasive cardiac test. The information submitted with respect to the previous noninvasive cardiac test must specify the type of test done prior to the PET scan and whether it was inconclusive or unsatisfactory. These explanations are in the form of special G codes used for billing PET scans using Rb 82. Beginning July 1, 2001, claims should be submitted with the appropriate codes.

B. Ammonia N-13

Effective for services performed on or after October 1, 2003, PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical ammonia N-13 are covered, provided the requirements below are met.

Requirements:

The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or

The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)

(This NCD last reviewed April 2003.)

V. Coverage of FDG PET for Lung Cancer

The coverage for FDG PET for lung cancer, effective January 1, 1998, has been expanded. Beginning July 1, 2001, usage of FDG PET for lung cancer has been expanded to include diagnosis, staging, and restaging (see section III) of the disease.

A. Effective for services performed on or after January 1, 1998, Medicare covers regional FDG PET chest scans, on any FDA approved scanner, for the characterization of single pulmonary nodules (SPNs). The primary purpose of such characterization should be to determine the likelihood of malignancy in order to plan future management and treatment for the patient.

Beginning July 1, 2001, documentation should be maintained in the beneficiary's medical file at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

Requirements:

There must be evidence of primary tumor. Claims for regional PET chest scans for characterizing SPNs should include evidence of the initial detection of a primary lung tumor, usually by computed tomography (CT). This should include, but is not restricted to, a report on the results of such CT or other detection method, indicating an indeterminate or possibly malignant lesion, not exceeding four centimeters (cm) in diameter.

PET scan claims must include the results of concurrent thoracic CT (as noted above), which is necessary for anatomic information, in order to ensure that the PET scan is properly coordinated with other diagnostic modalities.

In cases of serial evaluation of SPNs using both CT and regional PET chest scanning, such PET scans will not be covered if repeated within 90 days following a negative PET scan.

NOTE: A tissue sampling procedure (TSP) is not routinely covered in the case of a negative PET scan for characterization of SPNs, since the patient is presumed not to have a malignant lesion, based upon the PET scan results. When there has been a negative PET, the provider must submit additional information with the claim to support the necessity of a TSP, for review by the Medicare contractor.

B. Beginning July 1, 2001, Medicare covers FDG PET for diagnosis, staging, and restaging of NSCLC. Documentation should be maintained in the beneficiary's medical file to support the medical necessity of the procedure, as is normal business practice.

Requirements:

PET is covered in either/or both of the following circumstances:

Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.

Staging and/or Restaging - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when

it is expected that conventional study information is insufficient for the clinical management of the patient and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation should be maintained in the beneficiary's medical record at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

VI. Coverage of FDG PET for Esophageal Cancer

A. Beginning July 1, 2001, Medicare covers FDG PET for the diagnosis, staging, and restaging of esophageal cancer. Medical evidence is present to support the use of FDG PET in presurgical staging of esophageal cancer.

Requirements: PET is covered in either/or both of the following circumstances:

Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers as well as in melanoma should be rare.

Staging and/or Restaging - PET is covered in clinical situations in which 1)(a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending on the stage of the cancer identified.

PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation should be maintained in the beneficiary's medical record at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

VII. Coverage of FDG PET for Colorectal Cancer

Beginning July 1, 2001, usage of FDG PET for colorectal cancer has been expanded to include diagnosis, staging, and restaging of the disease (see part III).

A. Effective July 1, 1999, Medicare covers FDG PET for patients with recurrent colorectal carcinomas, which are suggested by rising levels of the biochemical tumor marker CEA.
   1. Frequency Limitations: Whole body PET scans for assessment of recurrence of colorectal cancer cannot be ordered more frequently than once every 12 months unless medical necessity documentation supports a separate re-elevation of CEA within this period.

2. Limitations: Because this service is covered only in those cases in which there has been a recurrence of colorectal tumor, claims for PET should include a statement or other evidence of previous colorectal tumor, through June 30, 2001.

B. Beginning July 1, 2001, Medicare coverage has been expanded for colorectal carcinomas for diagnosis, staging and re-staging. New medical evidence supports the use of FDG PET as a useful tool in determining the presence of hepatic/extrahepatic metastases in the primary staging of colorectal carcinoma, prior to selecting a treatment regimen. Use of FDG PET is also supported in evaluating recurrent colorectal cancer beyond the limited presentation of a rising CEA level where the patient presents clinical signs or symptoms of recurrence.

Requirements: PET is covered in either/both of the following circumstances:

Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.

Staging and/or Restaging - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

VIII. Coverage of FDG PET for Lymphoma

Medicare coverage of FDG PET to stage and re-stage lymphoma as alternative to a Gallium scan, was effective July 1, 1999. Beginning July 1, 2001, usage of FDG PET for lymphoma has been expanded to include diagnosis, staging and restaging (see section III) of the disease.

A. Effective July 1, 1999, FDG PET is covered for the staging and restaging of lymphoma.

Requirements:

PET is covered only for staging or follow-up restaging of lymphoma. Claims must include a statement or other evidence of previous diagnosis of lymphoma when used as an alternative to a Gallium scan

To ensure that the PET scan is properly coordinated with other diagnostic modalities, claims must include the results of concurrent computed tomography (CT) and/or other diagnostic modalities when they are necessary for additional anatomic information.

In order to ensure that the PET scan is covered only as an alternative to a Gallium scan, no PET scan may be covered in cases where it is done within 50 days of a

Gallium scan done by the same facility where the patient has remained during the 50-day period. Gallium scans done by another facility less than 50 days prior to the PET scan will not be counted against this screen. The purpose of this screen is to assure that PET scans are covered only when done as an alternative to a Gallium scan within the same facility. We are aware that, in order to assure proper patient care, the treating physician may conclude that previously performed Gallium scans are either inconclusive or not sufficiently reliable.

Frequency Limitation for Restaging: PET scans will be allowed for restaging no sooner than 50 days following the last staging PET scan or Gallium scan, unless sufficient evidence is presented to convince the Medicare contractor that the restaging at an earlier date is medically necessary. Since PET scans for restaging are generally done following cycles of chemotherapy, and since such cycles usually take at least 8 weeks, we believe this screen will adequately prevent medically unnecessary scans while allowing some adjustments for unusual cases. In all cases, the determination of the medical necessity for a PET scan for re-staging lymphoma is the responsibility of the local Medicare contractor.

Beginning July 1, 2001, documentation should be maintained in the beneficiary's medical record at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

B. Effective for services performed on or after July 1, 2001, the Medicare program has broadened coverage of FDG PET for the diagnosis, staging and restaging of lymphoma.

Requirements: PET is covered in either/both of the following circumstances:

Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.

Staging and/or Restaging - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

IX. Coverage of FDG PET for Melanoma

For services furnished on or after July 1, 2001 FDG PET is covered for the diagnosis, staging, and restaging of malignant melanoma (see part III). FDG PET is not covered for the use of evaluating regional nodes in melanoma patients.

A. Effective for services performed on or after July 1, 2001 FDG PET scan coverage for the diagnosis, staging and restaging of melanoma (not the evaluation regional nodes) has been broadened.

Limitations: **PET scans are not covered for the evaluation of regional nodes.**

Requirements: PET is covered in either/both of the following circumstances:

Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.

Staging and/or Restaging - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical file, as is normal business practice.

X. Coverage of FDG PET for Head and Neck Cancers

Effective for services performed on or after July 1, 2001, Medicare will provide coverage for cancer of the head and neck, excluding the central nervous system (CNS) and thyroid. The head and neck cancers encompass a diverse set of malignancies of which the majority is squamous cell carcinomas. Patients may present with metastases to cervical lymph nodes but conventional forms of diagnostic imaging fail to identify the primary tumor. Patients that present with cancer of the head and neck are left with two options either to have a neck dissection or to have radiation of both sides of the neck with random biopsies. PET scanning attempts to reveal the site of primary tumor to prevent the adverse effects of random biopsies or unneeded radiation.

Limitations: Refer to section XIV for coverage for thyroid cancer effective October 1, 2003.

Requirements: PET is covered in either/or both of the following circumstances:

Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging,

not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.

Staging and/or Restaging - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

XI. Coverage of FDG PET for Myocardial Viability

The identification of patients with partial loss of heart muscle movement or hibernating myocardium is important in selecting candidates with compromised ventricular function to determine appropriateness for revascularization. Diagnostic tests such as FDG PET distinguish between dysfunctional but viable myocardial tissue and scar tissue in order to affect management decisions in patients with ischemic cardiomyopathy and left ventricular dysfunction.

As of January 1, 2002, full and partial ring scanners are covered.

Beginning October 1, 2002, Medicare covers FDG PET for the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization, or following an inconclusive SPECT. Studies performed by full and partial ring scanners are covered.

Limitations: In the event that a patient has received a single photon computed tomography test (SPECT) with inconclusive results, a PET scan may be covered. However, if a patient received a FDG PET study with inconclusive results, a follow up SPECT is not covered.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

(See §50-58 of the CIM for SPECT coverage.)

XII. Coverage of FDG PET for Refractory Seizures

Beginning July 1, 2001, Medicare will cover FDG-PET for pre-surgical evaluation for the purpose of localization of a focus of refractory seizure activity.

Limitations: Covered only for pre-surgical evaluation.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

XIII. Breast Cancer

Beginning October 1, 2002, Medicare covers FDG PET as an adjunct to other imaging modalities for staging patients with distant metastasis, or restaging patients with locoregional recurrence or metastasis. Monitoring treatment of a breast cancer tumor when a change in therapy is contemplated is also covered as an adjunct to other imaging modalities.

Limitations: Effective October 1, 2002, Medicare continues to have a national non-coverage determination for initial diagnosis of breast cancer and staging of axillary lymph nodes.

Medicare coverage for staging patients with distant metastasis or restaging patients with locoregional recurrence or metastasis; and for monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is anticipated, is only covered as an adjunct to other imaging modalities.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

XIV. Thyroid Cancer

1. Effective for services furnished on or after October 1, 2003, Medicare covers the use of FDG PET for thyroid cancer only for restaging of recurrent or residual thyroid cancers of follicular cell origin that have been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and negative I-131 whole body scan performed.
2. All other uses of FDG PET in the diagnosis and treatment of thyroid cancer remain noncovered.

(This NCD last reviewed April 2003.)

XV. Soft Tissue Sarcoma - NOT COVERED

Following a thorough review of the scientific literature, including a technology assessment on the topic, Medicare maintains its national noncoverage determination for all uses of FDG PET for soft tissue sarcoma.

(This NCD last reviewed April 2003.)

XVI. Dementia and Neurogenerative Diseases - NOT COVERED

Following a thorough review of the scientific literature, including a technology assessment on the topic and consideration by the Medicare Coverage Advisory Committee, Medicare maintains its national noncoverage determination for all uses of FDG-PET for the diagnosis and management of dementia or other neurogenerative diseases

(This NCD last reviewed April 2003.)