

DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID & MEDICAL ASSISTANCE

DELAWARE MEDICAL ASSISTANCE PROGRAM

PHARMACY POLICY MANUAL

DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID & MEDICAL ASSISTANCE

Delaware Medical Assistance Program

Pharmacy Provider Specific Policy

Revision Table

Revision Date	Sections Revised	Description
7/1/02	All	Complete manual revision to reflect changes related to the MMIS and HIPAA compliance.
10/1/02	11.9, 11.19	Per the DUR Board we are deleting the prior authorization criteria for Filgrastim (11.9) and adding prior authorization criteria for Paform (11.19).
11/15/02	3.5.7	Adding clarification to non-covered service.
1/17/03	11.12. 11.17, adding 11.20	Clarifying prior authorization criteria policy
5/1/03	Added 3.2.4 and 3.4.3	Medicaid is limiting the quantity and duration of medications based on clinical appropriateness.
5/1/03	Added 11.21 and 11.22	Added prior authorization requirements for Selective Cox-2 Inhibitors and Proton Pump Inhibitors.
7/1/03	Adding 11.23	Adding prior authorization criteria for Enfuvirtide
7/1/02	Adding 11.24	Adding the Early Refill Request form, which has been used by providers since 7/1/02 but not accessible in the manual.
9/23/03	11.16 – 11.19	Updating prior authorization criteria for Oxycodone and Morphine Sustained Release Product, Fentanyl Transdermal, Medication Claims Over $500 and Synagis
1/1/04	Revised 3.1.1.3 and 11.22 – added 11.25	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
1/1/04	2.1.4	Coverage of OTC products/supplies for residents in a LTC facility is being clarified in Section 2.1.4. This policy is effective 1/1/04. Also clarifying the DMAC/FUL (effective 1/1/04).
1/10/03	3.1.1, 3.1.1.1, 3.1.1.2, 3.1.1.4, 4.1.1, 4.1.4, 4.1.4.1 – 4.1.4.5, deleted 4.1.4.6, added	Clarified the Reimbursement policy for pharmaceuticals.

Revision Date	Sections Revised	Description
	4.1.8	
1/13/04	11.8, 11.13, 11.15, 11.26, 11.27	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	11.28 and 11.29	Prior authorization requirements are being added for CNS Stimulants/atomoxetine and Lidocaine Topical Patch.
2/27/04	5.4.4.1	Revising the POS/DUR timely filing limit from 14 days to 100 days. This change will ease the administrative burden on the provider community and will reduce the time for clients to be reimbursed when their eligibility has been retroactively determined.
4/1/04	11.30	Prior authorization requirements are being added for Levalbuterol HCI (Xopenex).
5/25/04	11.13 and 11.31	The prior authorization requirements for Sevelamer are being revised. Prior authorization requirements are being added for Hemophilia Factor.
06/10/04	11.32 through 11.34	Prior Authorization requirements are being added for Eplerenone, Tiotropium bromide inhalation powder and Cinacalcet.
06/10/04	11.3-11.7, 11.10-11.12, 11.14-11.18, 11.20-11.24, 11.27-11.28	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: Sections 11.16, 11.17, 11.21, 11.27 and 11.28.
06/24/04	11.15, 11.26, 11.32	Adding language to the prior authorization requirements for Cholinesterase Inhibitor, DMARDS and Eplerenone.
07/28/04	11.28	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.
8/30/04	4.1.3	Pharmacies must give the DMAP credit for reusable medications returned to the dispensing pharmacy by a long term care facility.
9/29/04	11.35	Adding the prior authorization requirements for Duloxetine HCI. The requirements are effective immediately.
10/1/04	11.21	In the General Requirement section of the Selective Cox-2 Inhibitors Prior Authorization Form a change is made in the second co-morbid condition.
10/5/04	11.19	Synagis for pre-term babies section of the prior authorization requirements is being updated by inserting the word “first” in front of RSV season in three

Revision Date	Sections Revised	Description
		places.
11/3/04	11.7	This update changes the hematocrit level for chronic renal disease from 33% to 36% in the Restriction section of the Epoetin-Alpha prior authorization requirements.
1/12/05	11.36, 11.37	Two new Prior Authorization forms are being added: (1) Anti-Depressant for the Pediatric Patient and (2) Epidermal Growth Factor Inhibitors – Gefitinib (Iressa®) and Erlotinib (Tarceva®)
1/13/05	11.13	The prior authorization requirements for Sevelamer are being revised; additionally, the section title is changed to “Phosphorous Binders”.
1/18/05	11.38, 11.39, 11.40	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	11.41	One new Prior Authorization form/criteria is being added: Dronabinol.
1/26/05	11.42	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	11.36	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	11.43	One new Prior Authorization form/criteria is being added: Request for Quantity Limitation Override.
1/26/05	11.44	One new Prior Authorization form/criteria is being added: Tegaserod Maleate (Zelnorm®)
2/04/05	11.10, 11.35, 11.45	The prior authorization forms for Oral Antifungal and Duloxetine HCl have been removed. A prior authorization form for Step Therapy has been added.
2/11/05	11.13	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	11.13	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	11.46	Added Preferred Drug List (PDL) Override Form effective April 1, 2005.
3/31/05	ALL	The DMAP website address has been added to the

Revision Date	Sections Revised	Description
		header of all pages.
3/31/05	11.22	Effective April 1, 2005, Lansoprazole no longer requires Prior Authorization for daily or twice daily dosing.
3/31/05	11.44	Added a chart to the General Requirements section of the PA form for Tegaserod Maleate (Zelnorm®).
3/31/05	11.26	The prior authorization form for "Disease-Modifying Antirheumatic Drugs (DMARDS)" has been removed.
4/6/05	11.12, 11.14, 11.21, 11.28, 11.29	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	11.24	Changed the Pharmacy Team contact number to read 800-999-3371.
5/27/05	11.39, 11.47, 11.48, 11.32	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®)
8/22/05	11.6, 11.11, 11.12, 11.13, 11.15, 11.21, 11.34, 11.39, 11.47, 11.49, 11.50, 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.
9/15/05	Added new Section 4.2	Added client co-payment section. Effective date January 10, 2005, DMAP implemented a pharmacy co-payment. Effective July 1, 2005, DMAP implemented a monthly co-payment maximum.
10/14/05	11.21	Ankylosing Spondylitis has been added as a covered condition.
10/14/05	11.7, 11.13, 11.16, 11.17	The DMAP preferred product has been added to the top of each form.
10/14/05	11.51	The prior authorization form for Sildenafil has been added.
10/14/05	5.3.2.2.1	First Data Bank has been changed to MICROMEDEX.
10/20/05	Updated section 3.3.1. Added sections 3.3.1.4.1, 3.3.1.6, 3.4.1.1, 3.4.2.1-3.4.2.10, 3.4.3.1 and 3.4.3.2	Updated and added policy to reflect changes in the State Plan that establishes a preferred drug list.
10/20/05	Added new subsection 3.2.1.1	Added policy to reflect changes in the State Plan that include a supplemental rebate agreement.

Revision Date	Sections Revised	Description
11/23/05	11.52, 11.53, 11.54	Authorization forms have been added for Rozerem, Ambien CR and Symlin.
11/23/05	11.23	Removed the authorization form for Fuzeon.
11/23/05	11.28	The authorization form for CNS Stimulants and Atomoxetine has been updated to clarify the general requirements.
12/19/05	4.2.4.2.1, 11.43	The diagnosis code associated with pregnancy has been updated. Albuterol has been added to the Request for Quantity Limitation Override form.
1/24/06	11.55	Added a prior authorization form for Part D Override Requests.
2/2/06	4.1.4.3	Added clarification regarding pharmacy reimbursements.
3/21/06	3.5.8	Added policy regarding coverage of drugs to promote weight gain.
3/21/06	11.41	Replaced prior authorization form for Dronabinol with a prior authorization form for weight gain promoting agents.
3/21/06	11.11.1	The MedWatch Form has been moved from 11.12.1 to 11.11.1
4/11/06	11.47, 11.52, 11.53	Removed the prior authorization forms for Eszopiclone, Ramelteon and Zolpidem.
4/11/06	11.43	Removed the Pharmacy Limitation for Sedatives/Hypnotics.
5/15/06	11.16, 11.17	Avinza has been added as a preferred long acting opioid.
9/5/06	2.1.2, 3.1.1.3, 3.1.1.4, 3.3 (throughout), 3.4 (throughout), 3.5.2.1, 4.1.7 and 4.2.4.2.1	Adding clarification to existing policy.
11/8/06	11.2, 11.8,11.12, 11.13, 11.15, 11.21, 11.22, 11.25, 11.27, 11.28, 11.30, 11.33, 11.45, 11.49, 11.54	Added clarification to existing prior authorization forms. Authorization form for Step Therapy (11.45) was removed and reserved for future use.
11/8/06	11.56	Authorization form for Methylphenidate (DAYTRANA™) was added.

Revision Date	Sections Revised	Description
11/28/06	11.20, 11.57 and 11.58	Section 11.20 was updated. Authorization forms have been added for Insulin Human (Inhalation) Exubera® and (Sitagliptin phosphate) Januvia™
4/3/07	11.59, 11.60 and 11.61	Authorization forms have been added for Methadone (Methadose®), Naltrexone hydrochloride (Vivitrol™) and Pimecrolimus (Elidel®) and Tacrolimus (Protopic®).
5/31/07	6.0	Glucose monitors have been added to the inclusion list.
5/31/07	11.25, 11.49, 11.58, 11.62, and 11.63	Sections 11.25, 11.49 and 11.58 have been updated. Authorization forms have been added for Lubiprostone (Amitiza®) and Hepatitis C Agents.
6/25/07	11.16 and 11.17	The criteria for Oxycodone and Morphine Sustained Release Products and Fentanyl Transdermal have been updated.
10/5/07	11.8, 11.15, 11.21 and 11.60	The criteria forms for 5-HT3 Receptor Antagonists, Cholinesterase Inhibitors, Selective COX-2 Inhibitors and Naltrexone Hydrochloride have been updated.
10/5/07	2.1.2	Added newly mandated tamper resistant prescription pad policy
4/9/08	11.64 and 11.65	Authorization forms have been added for Maraviorac (Selzentry®) and Pregabalin (Lyrica®)
4/9/08	11.8, 11.16, 11.17, 11.28, 11.30 and 11.43	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	1.1 and 2.1	DMMA coverage for FDA approved indications and reversed prescription requirements.
8/14/08	2.1	Update to correct the wording associated with the listed publication examples.

Revision Date	Sections Revised	Description
8/14/08	6.0	Effective 9/5/08 cough and cold-oral, and diabetes supplies will be added to the PDL.
9/18/08	Manual Heading, 11.66 and 11.67	Removed obsolete numbering. Authorization forms have been added for Leukotriene Receptor Antagonists and Inhaled Glucocorticoid/Beta-Agonist Combination.
1/8/09	3.3.3 and 11.0	Updated the location to access specific criteria for prior authorization.
4/1/09	3.4.2.12	Added the Drug Utilization Review (DUR) Board's titration suggestion for reduction of the number of unique medications used per 30 days.
4/1/09	2.1.6, 4.1.4.2,	Added the policy changes that reflect reduced agency spending.
4/15/09	5.3.2.4	Change in overutilization rate from 75% to 83%.
6/5/09	3.3.2	Clarification and instruction provided to verify eligibility in emergency situations.
6/26/09	4.1.4.2	Effective 07/01/2009 updated the Estimated Acquisition Cost (EAC) for traditional and independent pharmacies.
10/30/09	3.3	Removed the reference to Appendix F.
11/11/09	4.1.4.2	Effective 10/14/2009 updated the Estimated Acquisition Cost (EAC) for traditional and independent pharmacies.
9/10/10	1.1.2.6 and 1.1.2.7	Added language to address pharmacy retro enrollment.
2/11/11	2.1.4	Clarification to the record retention policy.
3/14/11	2.1.7	Primary insurer clarification.
10/4/11	4.1.9	Guidance added to direct pharmacy providers to use diagnosis codes when billing, if on the prescription.
4/26/12	3.7	New section added regarding our policy on drug shortages.

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8/14/12	2.1.2.1	New section added regarding documentation for phoned in prescriptions.
10/16/12	4.1.7, 4.1.71., 4.1.7.2	New language and sections added clarifying that prescriptions may not be split into multiple prescriptions and dispensed.
10/18/12	3.4.2.3	Change in coverage of quantity and time frame.
11/9/12	1.1.2.2	Language added to specify requirements for validating the receipt of medication by the patient or patient's representative.
7/1/13	3.4.2.4.1	Effective July 1, 2013, added carisoprodol limits of 84 tablets per 90 days.
7/1/13	3.4.2.4.2	Effective July 1, 2013, baclofen will be excluded from the quantity limit.
5/8/14	4.1.4.1, 4.1.4.2, 4.1.4.3, 4.1.4.4 and 4.1.4.5	Update of reimbursement policy for dispensing pharmaceuticals and usual and customary definition.
6/1/14	3.0	Updated information on Delaware Maximum Allowable Cost to remove reference to Federal Upper Limit (FUL).
6/1/14	7.0, 8.0, 9.0, 10.0 and 11.0	Appendices B through F have been removed from the manual.
9/1/14	3.4.1.2	Added language to clarify limitations on prescriptions.
7/15/2015	1.1.2.3.1	Guidance added in regards to exemptions with Long Acting Reversible Contraceptives (LARC's)
7/15/2015	1.1.2.3.2	Language added to direct pharmacies on the dispensing of LARC's.
01/01/2016	4.1.10	Added new language to reflect the administration of immunization services by certified pharmacists effective 1/1/2016.
7/22/2016	Appendix A	Updated Category description from Lice Control Preparations to Topical Antiparasitics. Added additional Inclusions.
10/01/2017	2.1.8	Clarification added regarding the prohibition of cash payment for DMAP covered services.

Revision Date	Sections Revised	Description
7/01/2018	4.2	Added Naloxone opioid overdose rescue medications are excluded from the co-payment requirement for all Delaware Medicaid fee for service and Managed Care Organization (MCO) members.
08/01/2019	1.1.2.7	Added controlled substance prescribing and dispensing requirements in accordance with the Delaware Prescription Monitoring Act.
08/01/2019	All	Complete manual revision to align with the Delaware Medicaid Enterprise System (DMES) and the Delaware Medical Assistance Portal.
02/21/2022	2.0	Added language to specify requirements and limitations for 72-hour emergency prescription medication.
02/21/2022	3.0	Added language to specify requirements and limitations for 72-hour emergency prescription medication.
03/22/2022	4.2	Added Medication-Assisted Treatment (MAT) for opioid use disorder as a therapy excluded from the co-payment requirement for all Delaware Medicaid fee-for-service (FFS) and managed care organization (MCO) members.
09/23/2022	3.5.6.1	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.
11/30/2023	1.1.2.1	Clarification added regarding recoupment of monies for drugs that are systematically prepared but not used by the member.
11/30/2023	3.1.1 4.1.4.2	Updated language to change Wholesale Price (AWP) to Wholesale Acquisition Cost (WAC).
11/30/2023	4.1.8	Clarification added regarding DMAP coverage of Total Parenteral Nutrition under the medical benefit.
11/30/2023	4.2.4.2	Section updated in alignment with the State Plan regarding the expansion of post-partum coverage from 60 days to 12 months.
11/30/2023	4.2.4.2.1	Section updated in alignment with current ICD-10 diagnosis codes.
11/30/2023	4.2.4.8	Added smoking cessation products to copayment (copay) exclusions.
11/30/2023	5.3.2.4 5.3.2.4.1	Added controlled substance dispensing requirement for claim payment.

Revision Date	Sections Revised	Description
10/5/2026	All	Complete manual revision to align with current DMAP policy & procedure requirements.
10/5/2026	2.0	New section added regarding specific criteria for pharmacists as DMAP provider in alignment with the State Plan.
10/5/2026	3.8	New section added regarding specific criteria for the Cell & Gene Therapy Access Model in alignment with the State Plan.

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DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID & MEDICAL ASSISTANCE

Delaware Medical Assistance Program

Pharmacy Provider Specific Policy Manual

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Pharmacy Provider Specific Policy

1.0 Overview

1.1 General Criteria

This manual is to be used in conjunction with the **General Policy Manual**, **Pharmacy Billing Manual** and other provider specific manuals which are located on the **Delaware Medical Assistance Portal** and the **Pharmacy Corner**.

1.1.1 Pharmacy providers must meet all licensure requirements and have a license to practice pharmacy in the state in which they are located. They must comply with all regulatory requirements that affect pharmacy operators in their respective state. Each location must have a signed contractual agreement in place with the Delaware Medical Assistance Program (DMAP).

1.1.2 In addition:

1.1.2.1 The DMAP will only cover medications and pharmaceuticals dispensed directly to the DMAP member or the member's representative. The member or their representative must request medication. The DMAP reserves the right to recoup monies for drugs that are systematically prepared and subsequently not used by the member.

1.1.2.2 Cycle-filling for a DMAP member residing in a skilled nursing facility, group home, or assisted living arrangement does not constitute an automatic refill program. If the pharmacy and facility staff have a policy and procedure in place to prevent medication that is discontinued or otherwise unneeded from being billed, cycle-filling may be allowed on a case-by-case basis. Cycle-filling of medication that does not follow the policy and procedure between the pharmacy and facility may be subject to administrative action.

1.1.2.3 Pharmacy Providers must obtain a signature and the printed name of the member or their representative upon receipt of a covered medication.

1.1.2.4 Pharmacy providers are reminded that the member's Delaware Division of Medicaid and Medical Assistance (DMMA) card must be presented prior to the delivery of any services.

1.1.2.4.1 The pharmacy records must confirm that the identity of the individual who received the prescription was known to be the member or their representative.

1.1.2.4.2 The relationship with the member must also be part of the record.

1.1.2.4.3 The DMMA will recoup money when the required information is not on file.

1.1.2.4.4 Pharmacy providers must not dispense medications and pharmaceuticals to a member or the member's representative when the pharmacy provider is aware that the product will be administered in a hospital setting.

1.1.2.4.5 Long Acting Reversible Contraceptives (LARCs) are exempt from the requirements above.

1.1.2.4.6 Pharmacies may dispense LARCs to facilities on behalf of members.

1.1.2.5 Prescriptions that have not been received by the DMAP beneficiary or the representative of the beneficiary within fifteen (15) calendar days from the date the prescription is filled must be reversed so that the funds are returned to the DMMA. The date of service/ the date the prescription is filled is considered as day 1. The pharmacy must retain a record of the reversal on file for audit purposes.

1.1.2.6 If you are a pharmacy out of the Delaware area and have provided emergency services, the provider can request that the effective date of enrollment be back dated. The requested effective date must be approved by the Gainwell Technologies Pharmacy Coordinator. The requested effective date must be covered by any applicable license or certification submitted with this application.

1.1.2.7 There is no back dated enrollment for Traditional Delaware Pharmacy providers.

1.1.2.8 Pharmacy providers are required to review the Prescription Monitoring Program (PMP) patient utilization report with the receipt of every Schedule III-V prescription. Schedule II prescriptions should be reviewed each time unless the member is receiving these medications for a chronic illness. Medications prescribed for chronic illnesses should be monitored at least every three months. Chronic illness includes, but is not limited to, oncology, sickle cell-related diagnosis, and palliative care. Pharmacy providers must document that the PMP was reviewed and adhere to in-house documented protocols when the PMP indicates potential controlled substance abuse or a clinical issue.

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2.0 Pharmacy Program

2.1 Specific Criteria

2.1.1 The DMAP reimburses for legend drug items (i.e., those that require a prescription from a licensed practitioner), and certain categories of over-the-counter (OTC) products as listed on the DMAP pharmacy portal.

2.1.2 The DMAP will only reimburse providers for outpatient drugs when the written (non-electronic) prescription was executed on a tamper resistant pad following the DMAP tamper resistant pad guidelines. Electronic prescriptions are transmitted in the NCPDP script current version or sent as a fax. Verbal prescriptions are not impacted.

2.1.2.1 Prescriptions which are phoned in to the pharmacy must be documented in the patient record to minimally include: a) the name of the person who authorized or verified the prescription; b) the date the prescription was phoned in to the pharmacy; and c) the time of day the prescription was phoned in to the pharmacy.

NOTE: The only exception being drugs provided in institutional or group settings if the institutions and groups are validating all medications and dispensed quantities.

2.1.3 The DMAP will only reimburse claims for those legend and OTC drugs whose labeler is participating in the Federal Rebate Program. Providers who wish to obtain a list of participating labelers may contact Gainwell Technologies Pharmacy Services. Medical devices normally covered by DMAP such as diabetic supplies, syringes, and diaphragms may be limited to specific labelers/ manufacturers.

2.1.4 The provider must retain records for a period as designated in the provider contract to support the charge. Records include but are not limited to the original prescription, documentation of refills, wholesale/manufacturer invoices, and patient profiles, etc., for any claim for pharmaceutical products, non-prescription products, or medications covered by a standing order submitted to the DMAP. This data, where applicable, can be maintained electronically.

Reimbursement criteria for OTC medicines will be identical to those for prescription medicines. This means that for a DMAP member to receive a subsidized OTC product, he/she must have a valid prescription initiated by a medical practitioner authorized to prescribe by State law. In addition, the requirements for the pharmacists will be the same as those for a prescription product including profile entry, labeling, etc. Pharmacists should bill using the

Medicaid formula. Refer to the DMAP Over the Counter (OTC) Drug List on the DMAP Provider Pharmacy Corner.

Note: OTC products and all supplies (such as, but not limited to, lancets, syringes and diagnostic strips) for patients who are residents of certified and licensed intermediate or skilled care facilities are not reimbursable since these facilities are paid to provide these products to residents through per diem rates. Pharmacies cannot submit claims for OTC or Legend products that have an over-the-counter equivalent for members residing in a Long Term Care (LTC) facility. The state will recoup monies for over-the-counter and diabetic supplies that were billed to DMAP..

2.1.5 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.

2.1.6 DMAP is the payer of last resort. If the member has any additional prescription coverage, that entity must be billed first. Policies of the primary insurer (such as quantity limits, clinical authorization and guidelines) must be satisfied prior to submitting a claim to DMAP as non-covered by the primary insurer. (Additional directions for billing are provided in the DMAP Pharmacy Billing Manual.)

2.1.7 Providers are not permitted to charge or accept cash from members for any drug benefit that is covered by DMAP. If a delay in obtaining a prescription would endanger the health or welfare of the member, a 72-hour emergency prescription may be supplied to the member. An emergency supply is only dispensed once per drug per member during a 60-calendar day period.

2.2 Pharmacist Provider Qualifications

2.2.1 Effective January 1, 2025, in compliance with 24 Del. Admin. Code § 2500, pharmacists may enroll as DMAP providers. Pharmacists must affiliate with a pharmacy, group, practice, facility, or institution to bill services. Pharmacists must be listed as rendering providers. Pharmacists cannot bill for services. For more information about billing, see the Pharmacy Billing Manual.

2.2.2 "Prescriber" means a practitioner authorized to prescribe and acting within the scope of this authorization.

2.2.3 "Prescription" or "Prescription drug order" means the lawful written or verbal order of a practitioner for a drug, but does not include an order for medication

which is dispensed for immediate administration to the ultimate user, (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

2.3 Provider Qualifications

2.3.1 Eligible providers must operate within the scope of their professional license, and applicable state law.

2.3.2 Eligible providers must enroll with the Delaware Medical Assistance Program.

2.3.3 Services provided by pharmacy interns must be provided under the supervision of a licensed and registered pharmacist.

2.3.4 Telehealth providers must be in region (Delaware, Maryland, New Jersey, Pennsylvania, and Washington, D.C.) and must operate within the scope of applicable Federal and State laws.

2.4 Service Delivery Requirements

2.4.1 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.

2.4.2 Prescription (Drug Order) Information must meet the requirements of 24 Del. C. §2500.

2.5 Limitations for Pharmacists as Providers

2.5.1 Pharmacist seeking to “dispense” or “dispense and administer” under a DHSS Division of Public Health’s written standing order must meet the applicable State requirements.

2.5.2 Pharmacists seeking to “dispense” or “dispense and administer” hormonal contraceptives under the DHSS Division of Public Health’s written standing order must meet the requirements of 24 Del. Code Title 16 Chapter 30O and 24 Del. Admin. Code Title 16 §4110.

2.6 Reimbursement and Procedure Costs

2.6.1 When a diagnosis code is provided on a prescription, it must be entered on the claim.

2.6.2 Pharmacist Provider Services are reimbursed at 100 percent of the Medicaid Physician Services Fee Schedule.

2.6.3 See the Pharmacy Billing Manual for specific billing instructions.

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3.0 Limitations

3.1 Delaware Maximum Allowable Cost (DMAC)

3.1.1 DMAP has a limited DMAC program which is a list of products for which the DMAP has financial limitations. The DMAC applies when a National Average Drug Acquisition Cost (NADAC) price is not available and the Wholesale Acquisition Cost (WAC) does not reflect the purchase price of the drug. This list is available on the DMAP webpage. It should be noted, however:

3.1.1.1 The limits apply to drugs that have a DMAC.

3.1.1.2 Medicaid reimbursement is limited to only those drugs supplied from manufacturers that have a signed agreement or an approved existing agreement under Section 1927(a) of the Social Security Act.

3.1.1.3 Under most circumstances, brand medications will require prior authorization when a generic product is available. A completed Food and Drug Administration (FDA) Med-Watch form must be submitted for review.

3.1.1.3.1 In some situations, the branded product may continue to be the product covered on DMMA's PDL while the status of generic products may be non-preferred. A list of the Brand over Generic products is available on the DMAP Provider Pharmacy Corner.

3.1.1.4 When a provider wishes to override the limit due to the medical necessity of using the brand name product, refer to the Pharmacy Billing manual for instructions on the proper coding of the claim.

3.1.1.5 If the pharmacist is not willing to accept the DMAP's DMAC payment when a prescription is received for a brand product with no substitution permitted AND the physician has not indicated that the brand is medically necessary according to the DMAP requirement to qualify for a DMAC (price) Override, the member must be advised prior to the delivery of the service of the following options:

3.1.1.5.1 The physician may be contacted to provide the proper written documentation.

3.1.1.5.2 The member can take the prescription to another pharmacy that may be willing to fill the prescription for the DMAC price.

3.1.2 The DMAP newsletter and banner page on the RA (Remittance Advice) will be used to communicate any changes in the DMAC list. Pharmacy Providers can register for "Notify Me", the DMAP email notification via the Delaware

Medical Assistance Portal. Current pricing information for all drug codes is available on the DMAP Provider Pharmacy Corner.

3.2 Drug Rebate Programs

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

CMS has authorized the state of Delaware to participate in a supplemental rebate agreement with the Sovereign States Drug Consortium (SSDC) and to negotiate with labelers for outcome/value-based purchasing.

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

3.3 Prior Authorization Requirements

3.3.1 Medications may be identified as requiring prior authorization with recommendations from the Drug Utilization Review Board. Circumstances leading to the establishment of prior authorization criteria include, but are not limited to the following:

3.3.1.1 Medical necessity is not clearly evident.

3.3.1.2 Potential for diversion, misuse and abuse.

3.3.1.3 High cost of care relative to similar therapies.

3.3.1.4 Opportunity for unlabeled use defined as the use of a drug product in doses, patient populations, indications, or routes of administration that are not reflected in the FDA approved product labeling.

3.3.1.4.1 Medications may be limited to the maximum FDA approved dose.

3.3.1.4.2 Medications may be limited to the minimum FDA approved age limitations.

3.3.1.5 Drug classes where there is an identified potential for not being kept within the DMMA policy guidelines.

3.3.1.6 New drugs that come to market that are in one of the therapeutic categories covered by the Preferred Drug List.

3.3.1.7 The cost of the dispensed prescription exceeds $500.

3.3.2 Requests will be evaluated within one business day by DMAP's clinical staff. If required, one 72-hour emergency supply can be dispensed if a request is submitted when prior authorization is not available, and a delay would endanger the health or welfare of the member. An emergency supply is only dispensed once per drug per member during a 60-calendar day period. Eligibility should always be verified in emergency situations. Eligibility can be verified via the POS device, and through the Delaware Medical Assistance Portal for Providers. Refer to How-To: View and Verify a Member's Eligibility through the Provider Portal for assistance. Providers may also verify eligibility by using the Voice Response System (VRS) at 1-800-999-3371, option 1, regardless of the type of claim. The above three sources will provide either an eligibility or ineligibility response along with a verification number.

3.3.3 The Drug Utilization Review Board (DUR) 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 Delaware Medical Assistance Portal Pharmacy Corner for specific criteria for prior authorization.

3.4 Prescription Quantity

3.4.1 Prescriptions are limited to a quantity not to exceed the greater of 100 dosing units or a 90-day supply. A unit is defined as a single tablet, capsule, or other dosage form. DMMA may change quantity limits for medications to correspond to program initiatives to enhance patient compliance.

3.4.1.1 Medications that dose once a day are limited to one dose per day. DMMA will only reimburse for a 90-day supply.

3.4.1.2 Medications that dose less frequently than once per day (i.e. twice a week, weekly, once a month) will only be reimbursed for a 90-day supply.

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

3.4.3 Prescriptions must not be submitted to DMAP for payment if the pharmacist is aware that another payer has provided the medication for the same period. The pharmacist may not override the claim to submit the claim to DMMA without including the Coordination of Benefits showing the amount the primary insurance paid and the amount of the patient's responsibility. Failure to comply with this may cause monies to be recouped.

3.4.4 Delaware uses utilization management controls to promote efficient delivery of care and to control costs. Quantity limits exist for select categories of drugs. The Delaware Medicaid Preferred Drug List (PDL) is a complete list of the select drugs with limits and is available on the DMAP Provider Pharmacy Corner.

3.4.5 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.

3.4.6 Nicotine cessation products are limited to the FDA approved duration.

3.4.7 Palivizumab-is limited to 6 months during the high viral period of the year.

3.5 Non-Covered Services

3.5.1 Drug Efficacy Study Implementation (DESI) Drugs

3.5.1.1 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).

3.5.1.2 Providers who do not have a DESI drug list may obtain one by contacting Gainwell Technologies.

3.5.2 Drugs Used for Cosmetic Purposes

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

3.5.3 Fertility Drugs

3.5.3.1 The DMAP will not routinely reimburse for drugs that are prescribed to stimulate fertility for females or males.

3.5.4 Medical Necessity/Investigational Drugs

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

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

3.5.5 Compound Prescriptions

3.5.5.1 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.

3.5.5.2 Bulk active ingredient powders (API) are not covered as they are not from manufacturers that are in the Federal Drug Rebate Program.

3.5.5.3 Compounds with an ingredient cost of $150.00 dollars require prior authorization.

3.5.6 Drugs for Obesity

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

3.5.7 Prescriptions not generated by a DMAP provider may not be honored except in case of emergency where the member is out of the region. DMAP will only cover the cost of medical care that is either provided by or initiated by a practitioner enrolled in the program.

3.5.8 Drugs to Promote Weight Gain

3.5.8.1 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.

3.6 Sexually Transmitted Disease Drugs

3.6.1 The DMAP will cover pharmaceuticals indicated for eradicating the causative organism of a covered STD for those eligible for Family Planning and Related services when prescribed during a family-planning visit. Refer to the General Policy, Medicaid Eligibility Groups and Covered Services-Family Planning and Related Services for specific criteria.

3.7 Drug Shortage

3.7.1 Use the FDA website to confirm that the drug shortage has been registered. http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

3.7.1.1 If the posted information suggests that the shortage will be for minimal duration consider transferring the prescription to another pharmacy that may have the drug in stock.

3.7.2 Bio-equivalent products that are produced by multiple labelers, but are restricted based on the DMAP policy, can be addressed by contacting the Gainwell Technologies Provider Help Desk.

3.7.3 Pharmacists should contact the practitioner(s) when the prescriptions are for medications that are proprietary and where the duration of the shortage is either unknown or extensive.

3.7.4 Medications that are compounded due to a medication shortage must have the following indicated on the PA Compound Medication Form:

a) The medication is currently on back order,

b) AND

c) The active pharmaceutical ingredient (API) must be listed with the manufacturer and the national drug codes for all of the ingredients to be used in the compound. The compound must be priced at NADAC for each ingredient or DMAC, whichever is lower. WAC pricing must be used if NADAC or DMAC is not available.

3.8 Cell and Gene Therapy (CGT) Access Model

3.8.1 Cell and Gene Therapy (CGT) services are provided in accordance with the CGT Access Model to offer access to gene therapy treatments for people living with sickle cell disease, a genetic blood disorder. The FDA currently only approves CGT for people living with sickle cell disease. Provider should carefully read and adhere to the following instructions to ensure accuracy, completeness, and clarity so that claims can be processed efficiently.

3.8.2 Provider Qualifications

3.8.2.1 The following provider types are eligible to prescribe the CGT treatment services:

- Hematology / Internal Medicine – Hematology & Oncology Physician
- Pathology – Hematology Physician
- Pediatric Hematology-Oncology Physician

3.8.2.2 The following provider types are eligible to render CGT-associated services:

- Hematology / Internal Medicine – Hematology & Oncology Physician
- Pathology – Hematology Physician
- Pediatric Hematology-Oncology Physician
- Hematology Specialist / Technologist
- Hemapheresis Practitioner
- Psychologist
- Psychiatrist
- Social Worker

3.8.2.3 The following provider types are eligible to bill for CGT services. The facility must be certified by the CGT pharmaceutical manufacturer(s).

- Acute Care Inpatient Hospital
- General Acute Care Hospital
- Specialty Hospital
- Military Hospital

3.8.2.4 Eligible providers must enroll with the Delaware Medical Assistance Program.

3.8.2.5 Eligible providers must operate within the scope of their professional or facility license, board certification, and applicable state laws.

3.8.2.6 Eligible hospital facility providers must provide certification from the CGT pharmaceutical manufacturer(s).

3.8.3 Service Delivery Requirements

3.8.3.1 CGT services must include the following:

- A face-to-face in-person or telehealth encounter with the prescribing physician who specializes in sickle cell disease,
- Comprehensive assessment related to sickle cell disease and CGT,
- Pre-infusion evaluation and management services, and

- Post-infusion periodic evaluation and management services to monitor and document outcomes from interventions.

3.8.4 Limitations

3.8.4.1 There is a limit of one (1) treatment per member per lifetime.

3.8.4.2 This service limit may be exceeded based on medical necessity.

3.8.5 Prior Authorization

3.8.5.1 Prior Authorization is required. All services must be based on medical necessity with a board-certified Hematology Physician's order.

3.8.5.2 Prior authorization must be obtained before initiating services. Failure to obtain prior authorization before delivery of services will result in no reimbursement for the services.

3.8.5.3 For Fee-for-Service (FFS) members, prior authorization must be submitted electronically via the DMAP Provider Portal at https://Medicaid.dhss.delaware.gov/ before initiating services.

3.8.5.4 For Managed Care Organization (MCO) members, prior authorization must be submitted to the member's MCO before initiating services. Refer to the relevant MCO's Provider Manual for specific instructions.

3.8.6 Billing

3.8.6.1 All services must be billed separately. The cost of the drug must be billed separately from all other services and must be billed FFS.

3.8.6.2 The cost of the drug will be reimbursed according to the current DMAP drug reimbursement methodology.

3.8.6.3 For FFS members, inpatient hospitalization will be reimbursed at the inpatient bundled rate for the facility. If the patient requires subsequent hospitalization after the initial stay involving the CGT service, reimbursement will follow the applicable inpatient bundled rate for the facility. Other services and/or products will only be reimbursed if:

- The service or product not already included in the cost of the drug, and
- The services were rendered prior to the member's inpatient stay. Examples of services rendered prior to the member's inpatient stay include apheresis, chemotherapy, cell engineering, leukapheresis, and preparative therapy. This list is not all-inclusive.

3.8.6.4 For MCO members, all services and/or products excluding the drug must be submitted as an MCO claim. The MCO member's inpatient hospitalization will be reimbursed at the inpatient bundled rate for the facility. If the patient requires subsequent hospitalization after the initial stay involving the CGT service, reimbursement will follow the applicable MCO inpatient bundled rate for the facility.

3.8.6.5 The 340B program does not apply to CGT medications listed in CGT Access Model. The CGT medications are carved out of the 340B model and do not qualify for 340B discounts, as they are reimbursed directly via FFS. Providers may not claim 340B discounts on CGT medications used under the CGT Access Model.

3.8.6.6 For more information, see the Pharmacy Billing Manual: https://medicaidpublications.dhss.delaware.gov/docs/search?EntryId=33.

4.0 Reimbursement

4.1 Methodology and Provider Charges

4.1.1 Pharmacy providers must bill using National Drug Codes (NDCs). Entities that qualify for special purchasing under Section 602 of the Veterans Health Care Act of 1992, Public Health Service covered entities, selected disproportionate share hospitals and entities exempt from the Robinson-Patman Price Discrimination Act of 1936 must charge the DMAP no more than an actual acquisition cost (AAC) plus a professional dispensing fee. The AAC must be supported by invoices and payment documentation.

4.1.2 Compounded drug products may be billed to DMAP. Refer to the Billing Instructions of this manual for instructions on billing these prescriptions.

4.1.3 When prescriptions are filled but can later be reused by the pharmacy, the pharmacy must credit the DMAP by adjusting the claim(s) or refunding through a check. Medications that are returned from a Long-Term Care facility and can be reused (according to State Law) must be credited to the DMAP. The check should be sent payable to the State of Delaware and addressed to the Division of Medicaid and Medical Assistance (DMMA) office. It is preferred that the providers submit adjustments so that the history is correct. This is particularly important for possible future auditing activities. If a check is submitted, the provider must keep accurate records that associate the refund with the specific prescription.

4.1.4 For covered pharmaceuticals, the DMAP will reimburse the lower of:

4.1.4.1 The usual and customary (U&C) charge to the public for the prescription

USUAL AND CUSTOMARY (U&C) – is defined as the lower of

- amount charged to a cash paying customer
- amount charged to customers enrolled in the provider's discount program
- contracted rates with Delaware State employees' groups
- contracted rates for any Federal employee groups

4.1.4.2 National Average Drug Acquisition Cost (NADAC) or if a NADAC is not available, the Wholesale Acquisition Cost (WAC) for legend drugs, or Wholesale Acquisition Cost minus 2% for non-legend drugs.

4.1.4.3 A state specific maximum allowable cost (DMAC).

4.1.4.4 AAC plus a dispensing fee for entities that qualify for special purchasing.

4.1.5 Enfit products are only covered when ordered by a licensed provider and will be reimbursed per DMMA policy at NADAC, SMAC, or WAC whichever is lower

4.1.6 A dispensing fee will be applied to all claims for the first fill of the month regardless of the day supply. No dispensing fee will be paid to any pharmacy for additional claims for the same medication and member within the 30-day period.

4.1.7 Legend products to Intermediate or Nursing Facility (NF) patients are currently billed and reimbursed by the same methodology; however, such facilities are reimbursed for OTC products through the per diem. Therefore, pharmacy providers are prohibited from billing OTC products for ICF/NF. DMMA will not pay for legend products when an over-the-counter version of the medication is available as house stock.

4.1.8 The Point of Sale (POS) program is mandatory for any provider who dispenses to an ambulatory member. An ambulatory member is defined as anyone not residing in a facility that follows the administrative requirements of OBRA'89.

4.1.9 Prescriptions may not be split into multiple prescriptions to be dispensed concurrently.

4.1.9.1 Supplies for multiple locations such as a school or adult care center should not be dispensed as a separate prescription. If separate packaging is required, the pharmacy should use duplicate labels.

4.1.9.2 Prescriptions may not be divided for part to be paid by the member and part to be paid by DMAP. A member who chooses to pay out of pocket must pay in full for the complete prescription.

4.1.10 Total Parenteral Nutrition (TPN), which includes parenteral supplies and enteral products, must be billed by and reimbursed to providers enrolled as Durable Medical Equipment (DME) Suppliers only.

4.1.11 When a diagnosis code is provided on a prescription, it must be entered on the claim.

4.1.12 Allowed billing methodology:

4.1.12.1 White Bagging is when a provider orders medication for a DMAP member and has it delivered to a facility or office for administration. The provider must bill for the cost of the medication if not paid for in another transaction and the administration fee. This is DMAP's preferred method.

4.1.12.2 Clear Bagging is when a provider orders a medication from the pharmacy of the health system with which they are affiliated. The pharmacy bills for the medication, and the provider bills for the administration fee.

4.1.12.3 Gold Bagging is when a provider orders medication from the specialty pharmacy of the health system with which they are affiliated, and the high-cost specialty medication is delivered to the provider's office. The specialty pharmacy bills for the medication, and the provider bills for the administration fee.

4.1.13 Disallowed billing methodology:

4.1.13.1 Brown Bagging is when a pharmacy gives medication to the DMAP member to take to the physician to be administered. The pharmacy bills for the medication, and the treating provider bills for the administration fee. Brown Bagging is not allowed due to possible temperature and storage issues that may occur to the medication during transport and to prevent potential for fraud, waste, and abuse.

4.1.14 Adult vaccines administered by a certified pharmacist are covered based on the ingredient cost of the vaccine and the administrative charge equal to that of the professional dispensing fee.

4.2 Drugs Carved Out of Inpatient Per Diem

4.2.1 DMMA carves out certain drugs for the inpatient per diem. These drugs must be separately reimbursed when administered in an inpatient setting. DMAP does not allow for bundle billing of the specified drugs.

4.2.2 Some drugs on the High Investment Cost list may require prior authorization (PA) before being administered to the member. PAs for MCO members must be submitted to the MCO. PAs for DMAP members must be submitted electronically via the DMAP Provider Portal.

4.2.3 MCO claims must be submitted to the member's MCO and will be reviewed by the MCO. FFS claims must be submitted electronically via the DMAP Provider Portal and will be reviewed by DMMA. These carved out drugs are reimbursed at the actual acquisition cost (AAC).

4.2.4 To receive separate reimbursement for drugs carved out of the inpatient per diem administered during inpatient hospital stays, providers must submit an outpatient or pharmacy claim with the most appropriate National Drug Code (NDC), drug name, quantity administered, and J code.

4.3 Member Co-Payment

4.3.1 All States are permitted to require certain members to share some Medicaid cost by imposing upon them such payments as enrollment fees, premiums, deductibles, coinsurance, co-payments or similar cost sharing charges as referenced in section 1902(a)(14) of the Social Security Act.

4.3.2 All DMAP members, other than those specifically excluded, are liable for sharing the cost of DMAP covered prescription drugs as well as over-the-counter drugs prescribed by a practitioner. DMAP members are required to pay a specific pharmacy co-payment amount for each prescription filled at a pharmacy participating in the DMAP. In accordance with 42 CFR § 447.54, the pharmacy co-payment amount is based on the Medicaid fee for the drug being dispensed. The co-payment is imposed for each drug that is prescribed and dispensed. The co-payment amounts imposed are as follows:

Medicaid Payment for the Drug	Co-Payment
$10.00 or less	$.50
$10.01 to $25.00	$1.00
$25.01 to $50.00	$2.00
$50.01 or more	$3.00

4.3.3 All co-payments imposed on a DMAP member for prescription drugs and prescribed over-the-counter drugs are capped at $15 per calendar month. Once the member pays $15 in copays, all remaining copays must be zero ($0) for the remainder of the calendar month.

4.3.4 The following individuals, services, and medication treatments are excluded from the Medicaid fee for service and Managed Care Organization (MCO) co-payment requirement, as referenced in 42 CFR § 447.53:

4.3.4.1 Individuals under 21 years of age.

4.3.4.2 Pregnant women, including the postpartum period (12 months).

4.3.4.2.1 Pharmacists who are aware that the member is pregnant must use the ICD-10 diagnosis code Z33.1 to override the copayment amount. In the postpartum period, the pharmacist must use the ICD-10 diagnosis code Z37.9 to override the copayment amount.

4.3.4.3 Individuals eligible under the long-term care nursing facility group or the acute care hospital group.

4.3.4.4 Family planning services and supplies.

4.3.4.5 Hospice services.

4.3.4.6 Naloxone opioid overdose rescue medications.

4.3.4.7 Medication-Assisted Treatment (MAT) used for Opioid Use Disorder.

4.3.4.8 Smoking cessation products.

4.3.4.9 Vaccines recommend by the Advisory Committee on Immunization Practices (ACIP) for adults aged 21 or older.

4.3.5 All pharmacies will be advised via the Point-of-Sale System regarding the member's liability for the drug co-payment and the amount of the co-payment.

4.3.6 If a member advises a pharmacy of an inability to pay the applicable co-payment at the time the prescription is filled, pharmacies cannot refuse to fill the prescription(s) and must dispense the prescription(s) as written, per 42 CFR § 447.53(e).

4.3.6.1 Members will remain liable for the co-payment amount and will be responsible for paying the pharmacy when financially able. The pharmacy provider is permitted to pursue reimbursement of the co-payment amount from the recipient.

4.3.6.2 Provider payment will be reimbursed as the DMAP fee minus the applicable member co-payment amount. DMAP will not pay the co-payment amount to the pharmacy when a member declares an inability to pay.

5.0 Drug Utilization Review (DUR) Policy

5.1 Introduction

5.1.1 The Drug Utilization Review (DUR) section of this manual defines the regulations and policies developed specifically for the State of Delaware and DMAP. It should be noted that, in all services delivered under the DMAP, the provider must comply with the DMAP requirements AND with all applicable State laws.

5.2 General Overview

5.2.1 The U.S. Congress enacted the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) on November 5, 1990. This legislation contains thirteen titles addressing a variety of areas. Many provisions included in Section 4401 of OBRA '90, however, directly affect Medicaid pharmacy programs and Medicaid pharmacy providers. In short, the framers of OBRA '90 are counting on the strength of Drug Utilization Review (DUR) to assure quality care and reduce medical costs within State Medicaid Programs.

5.2.2 OBRA '90 commissions two types of DUR. Section 1927 (g)(2)(A) of the Act contains the requirements for prospective drug review (PRO-DUR). This statute requires State programs to provide for comprehensive review of drug therapy before filling each member's prescription. Sections 1927(g)(2)(B) of the Act contain requirements for retrospective drug use review (RetroDUR), which provides for ongoing periodic examinations of claims and other records to identify patterns of fraud, abuse, gross overuse, inappropriate or medical unnecessary care, among physicians, pharmacists, and individuals receiving Medicaid benefits.

5.2.3 PRO-DUR and RetroDUR are separate processes. They complement each other, however, in monitoring appropriate drug usage. PRO-DUR systems help prevent potentially dangerous therapeutic conflicts at the point of sale. RetroDUR assists in the identification and reversal of long-term harmful and/or costly trends that are usually not discernible at the time of dispensing.

With the introduction of the National Council for Prescription Drug Programs' (NCPDP) new pharmacy telecommunications that is the current standard, however, many inputs/outputs from PRO-DUR systems are more meaningful when viewed in RetroDUR systems.

5.2.4 OBRA '90's PRO-DUR language requires State Medicaid provider pharmacists to review Medicaid member's entire drug profile before filling their prescription(s). OBRA '90 requires evaluation of the following drug therapy problems: therapeutic duplication; drug-disease contraindications; drug-drug interactions (including serious interactions with nonprescription or OTC drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and evidence of clinical abuse/misuse.

5.2.5 To comply with OBRA '90's PRO-DUR requirements, State Medicaid agencies must adapt criteria and standards (to detect these conditions) from the following sources: American Hospital Formulary Service Drug Information, the United States Pharmacopoeia-Dispensing Information, the American Medical Association Drug Evaluations, and other peer-reviewed medical literature.

5.3 Prospective Drug Utilization Review

5.3.1 While State Medicaid agencies will set up the programs mandated by OBRA '90, pharmacy providers are responsible for performing many required provisions. In support of State Medicaid members, OBRA '90 requirements make pharmacists responsible for Therapeutic Screening, Patient Counseling and Maintaining Proper Patient Records.

5.3.2 Therapeutic Screening - Dispensing pharmacists are responsible for conducting therapeutic screenings before filling prescriptions. Pharmacists may use explicit written criteria or the Delaware Medicaid Enterprise System (DMES) criteria-based computer software to conduct prospective DUR. Delaware's therapeutic screening detection system alerts pharmacists of the following potential conflicts:

5.3.2.1 Drug-Drug Interaction Alerts **-**Delaware's automated therapeutic screening system transmits electronic messages (warnings) to the dispensing pharmacist when a member's simultaneous use of two or more drugs will create a different pharmacological response than when each drug is given separately. DMES drug-drug interaction edits are performed at the generic ingredient level to ensure the screening is as complete as possible.

5.3.2.1.1 Methods used in Drug-Drug Interaction Detection – DMES captures the Member ID from submitted claims and matches these values with historical claim records to assemble drug history profiles for the current member. The system then compares this member's historical data to the submitted claim and searches for agents known to create in a drug-drug interaction with the current claim. Detection may be complicated with erroneous (false positive) results if the efforts are not made or exclude discontinued therapies in the edit process. Therefore, DMES applies a variable percent to the days' supply of all historical claims, which compensates for the time drugs remain in the member's system beyond final consumption. A warning will not be sent to the pharmacy if the prescriptions were written by the same prescriber and are filled at the same pharmacy.

5.3.2.1.2 Output of Conflict Detection - In response to claims that trigger drug-drug interaction alerts, Delaware's MMIS will transmit a DUR drug-drug interaction alert message. This alert message will contain the drug-drug interaction alert conflict code of "DD".

5.3.2.2 Incorrect drug dosage or duration of treatment (Low/High Dose Alert) – Delaware's automated therapeutic screening system transmits electronic messages (alerts) to the dispensing pharmacist when it detects a dosage below/above a minimum/maximum effective dosage being dispensed to a DMAP member.

5.3.2.2.1 Detection of Conflict – DMES evaluates the therapeutic drug regimens by comparing the dose and frequency of administration (which produce optimal plasma levels based upon the patient's clinical status) to the dose being dispensed by the pharmacist. The quantity dispensed is divided by the day's supply to obtain units per day (UPD). The UPD is compared to the minimum/maximum daily dosage value from MICROMEDEX's Min/Max Module. An alert condition results if the UPD is below/above the minimum/maximum daily units.

5.3.2.2.2 Output of Conflict Detection - In response to on-line real-time claims submissions for drugs that trigger Low/High Dose alerts, DMES will transmit a DUR Low/High-Dose alert message. This alert message will contain the conflict code of "LD" or "HD".

5.3.2.3 Therapeutic Duplication - Delaware's automated therapeutic screening system transmits electronic messages (warnings) to the dispensing pharmacist when a member's simultaneous use of two or more drugs will result in therapeutic overlap (duplication of therapy). A therapeutic overlap exists when a member is simultaneously treated with two drugs with similar ingredients that share the same therapeutic class and route of admission.

5.3.2.3.1 Detection of Therapeutic Duplication - DMES captures the Member ID from submitted claims and matches these values with historical claim records to assemble drug history profiles for the member. The system then searches this historical data extract for agents sharing identical routes of administration and therapeutic class with the current claim. If both values match, the system compares the generic drug identifications of the two drugs. If these generic drug identification values are not equal, a duplication of therapy exists. A warning will not be sent to the pharmacy if the prescriptions were written by the same prescriber and are filled at the same pharmacy. If these generic drug identification values are equal, the prescription is subject to evaluation for timeliness of refill. Medications with the same mechanism of action may be subject to prior authorization.

5.3.2.3.2 Output of Conflict Detection - In response to on-line real-time claims submission for drugs that trigger duplication of therapy alerts, DMES will transmit a DUR therapeutic duplication alert message. This alert message will contain the therapeutic duplication alert conflict code of "TD".

5.3.2.4 Overutilization Alerts - Delaware's automated therapeutic screening system transmits electronic messages to the dispensing pharmacist when

members obtain excessive (early) refills and/or abuse their benefits. Controlled substances in Schedule II to V must have used 90% of the prescription (based on the day supply) before the claim will pay. This edit identifies claims submitted for additional supplies of identical medications when the patient has consumed less than 83% of the original prescription. These medications will not be covered by the DMAP pharmacy benefit unless there is a change in direction or an extraordinary situation. The drugs would be covered via the prior authorization process.

5.3.2.4.1 Detection of Overutilization - DMES captures the Member ID from submitted claims and matches these values with historical claim records to assemble drug history profiles for the member. The system then searches this historical data extract for agents sharing identical routes of administration and therapeutic class with the current claim. If both values match, the system compares the generic drug identifications of the two drugs. If these generic drug identification values are equal, the prescription is a continuation of the same medication. The most recent date of service (DOS) helps estimate the days' supply remaining from the previous fill. If this estimate indicates that at least 83% of the previous fill have not been used, the system prepares and sends an overutilization alert to the pharmacist. Controlled substances in Schedule II to V must have used 90% of the prescription (based on the day supply) before the claim will pay.

5.3.2.4.2 Output of Conflict Detection - In response to on-line real-time claims submission for drugs that trigger overutilization alerts, DMES will transmit a DUR Early Refill alert message. This alert message will contain the overutilization alert conflict code of "ER". System capability will be provided for authorized overrides.

5.3.2.5 Underutilization Alerts - Delaware's automated therapeutic screening system transmits electronic messages (warnings) to the dispensing pharmacist when subtherapeutic patterns of prescription use are detected.

5.3.2.5.1 Detection of Underutilization - DMES captures the Member ID from submitted claims and matches these values with historical claim records to assemble drug history profiles for the member. The system then searches this historical data extract for agents sharing identical routes of administration and therapeutic class with the current claim. If these values match, the system compares generic drug identifications of the two agents. If these generic drug identification values are equal, the prescription is recognized as a continuation of the same medication. The most recent date of service (DOS) and days supply (DS) values are then used to evaluate if the refill is "on time". For example, if the previous fill was submitted as a thirty-day supply and it has taken the patient forty days to initiate the refill process, this is considered a late refill.

5.3.2.5.2 Output of Conflict Detection - In response to on-line real-time claims submission for drugs that trigger underutilization alerts, DMES will transmit a DUR alert message. This alert message will contain the underutilization alert conflict code of "LR".

5.3.2.6 Drug-Disease Alerts - Delaware's automated therapeutic screening system transmits electronic messages (warnings) to dispensing pharmacists when certain drugs are utilized for patients with specific medical conditions. Delaware's Drug-Disease ProDUR software will interface with inferred diagnoses (based on drug history) or with reported medical history (derived from medical claim data).

5.3.2.6.1 Detection of Drug-Disease Conflicts - DMES collects diagnostic data from actual medical claims (or infers the diagnosis from historical pharmacy claims) and adds it to the member's medical history. Members' medical histories consist of ICD-10 (diagnosis) codes with associated dates of service. When a claim is submitted, it is compared to these diagnostic tables. If the active ingredients of the current prescription are found to aggravate (or worsen) an existing diagnosis, the system will send a drug-disease alert to the dispensing pharmacist. Additionally, DMES maintains disease state duration tables, which show the average duration of illnesses reported with ICD-10 codes. Using dates of service and this duration parameter, the system edits member medical conditions to ensure an active diagnosis.

5.3.2.6.2 Output of Conflict Detection - In response to on-line real-time claims submissions for drugs that trigger Drug-Disease alerts, DMES will transmit a DUR Drug-Disease alert message. This alert message will contain either the conflict code of "MC" (if the diagnosis was reported in medical records) or "DC" (if the diagnosis was inferred from drug history profiles).

5.3.2.7 Drug-Age Alert - Delaware's automated therapeutic screening system transmits electronic messages (warnings) to the dispensing pharmacist when prohibited drugs are dispensed for a given age group of patients.

5.3.2.7.1 Detection of Conflict - Very old or very young people should not use certain drugs. DMES maintains a master listing of these drugs in their system and by comparing submitted claims (and the date of birth of the member) to the drugs on the age conflict master list, the DMES warns pharmacists of these problems.

5.3.2.7.2 Output of Conflict Detection - In response to on-line real-time claims submissions for drugs that trigger Drug-Age alerts, DMES will transmit a DUR Drug-Age alert message. This alert message will contain the conflict code of "PA".

5.3.2.8 Drug-Pregnancy Alerts - Delaware's automated therapeutic screening system transmits electronic messages (warnings) to dispensing pharmacists when certain drugs are utilized for patients with specific medical conditions. Delaware's Drug-Pregnancy PRO DUR software will interface with the inferred diagnosis of pregnancy (based on drug history) or with reported medical history of pregnancy (derived from medical claim data).

5.3.2.8.1 Detection of Drug-Pregnancy Conflicts - DMES collects diagnostic data from actual medical claims (or infers the diagnosis from historical pharmacy claims)

and adds it to the member's medical history. Member medical histories consist of ICD-10 (diagnosis) codes with associated dates of service. When a claim is submitted, it is compared to these diagnostic tables. If the active ingredients of the current prescription are found to be toxic to a pregnant woman, the system will send a drug-pregnancy alert to the dispensing pharmacist.

5.3.2.8.2 Output of Conflict Detection - In response to on-line real-time claims submission for drugs that trigger Drug-Pregnancy alerts, DMES will transmit a DUR Drug-Pregnancy alert message. This alert message will contain the conflict code of "PG".

5.3.2.9 Reserved

5.3.3 Patient Counseling Standards

5.3.3.1 OBRA '90 also requires a state to establish standards governing patient counseling. Dispensing pharmacists must offer to discuss the unique drug therapy regimen of each DMAP member when filling prescriptions for them.

5.3.3.2 Such discussions must include matters that are significant, in the professional judgement of the pharmacist, including, but not limited to, the following: name and description of the medication, route of administration, dose, dosage form, and duration of drug therapy. OBRA '90 also mandates that pharmacists discuss special directions and precautions for preparation of drugs, administration and use by the patient; common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered (including their avoidance and the action required if they occur); techniques for self-monitoring drug therapy, proper storage; refill information; and appropriate action in case of a missed dose. By enhancing communication between pharmacists and patients, counseling may contribute to improved patient compliance.

5.3.3.3 Providers must comply with all relevant state laws.

5.3.4 Maintenance of Patient Records

5.3.4.1 Under OBRA '90 Medicaid pharmacy providers also must make reasonable efforts to obtain, record, and maintain at least the following DMAP patient information:

5.3.4.1.1 Name

5.3.4.1.2 Address

5.3.4.1.3 Telephone number

5.3.4.1.4 Age and gender

5.3.4.1.5 Individual history (where significant), including disease state or states

5.3.4.1.6 Known allergies and/or drug reactions

5.3.4.1.7 A comprehensive list of medications and relevant devices

5.3.4.1.8 The pharmacist's comments about the individual's drug therapy

5.3.4.2 By maintaining such profiles, pharmacists can more effectively counsel patients on drug therapy.

5.4 Point of Sale System Operations

5.4.1 Submission Process

5.4.1.1 Members will take their prescription to any participating provider pharmacy and present proper identification to request prescription service. The pharmacy will enter the member identification and the prescription information into the pharmacy computer or point of sale (POS) device and transmit the claim to DMES via approved telecommunication routes.

5.4.1.2 The claim must contain the required information in the National Council for Prescription Drug Programs (NCPDP), based on DMAP's approved transaction specifications.

5.4.1.3 If no error or DUR alert condition is found during the adjudication process, the pharmacy will receive an NCPDP defined response message advising:

5.4.1.3.1 The amount of reimbursement and co-pay (if applicable)

5.4.1.3.2 A POS adjudicated response authorization number assuring the pharmacy will receive payment.

5.4.1.4 If the DMES software detects an exception to the PRO DUR criteria, an alert message will be sent to the pharmacist. If the pharmacist feels the condition is correctable through conversation with the prescribing physician or the patient, the pharmacist will resubmit the claim with corrected information or a DUR response explaining the resolution of the problem.

5.4.1.5 When receiving PRO DUR alerts, pharmacists must use professional judgement to decide whether the prescription should be filled. The pharmacist may confer with the patient, call the prescriber, consult the DUR manual, refer to other professional references, or call the Delaware help desk to obtain additional information on which to base action.

5.4.2 Adjudication Process

5.4.2.1 When claims are received, DMES system will invoke a series of programs that read files and perform edits equivalent to those currently performed in the State's batch claims processing system. On-line real-time edits occur within a few seconds, and responses are prepared based on the submitted information and appropriate historical information. Details of adjudication steps follow:

5.4.2.1.1 The system will read the provider master file to decide if the pharmacy is enrolled in the DMAP.

5.4.2.1.2 The system will initiate a member eligibility query. Only prescriptions generated by a practitioner who is enrolled as a provider in the Managed Care Organization (MCO) panel will be honored for members enrolled in the Diamond State Health Plan (DSHP).

5.4.2.1.3 The system will read the pharmacy on-line history file referring 130 days and the POS adjudicated file to check for claims already adjudicated for this member. The system will determine whether the claim has already been paid. If it passes this duplicate check, other history audits will be performed. Each prescription record will be maintained in the history file for analysis in the DUR module.

5.4.2.1.4 To complete the member's medical history (for DUR analysis), the system will integrate the member's medical profile, which contain diagnoses, procedures, and date of service for medical claims.

5.4.2.1.5 Delaware's Prospective DUR module applies rules for use of the prescribed drug with the member's drug history and diagnostic data. After detecting potentially dangerous or wasteful conditions, the appropriate message is generated (in NCPDP approved response format) and transmitted to the provider pharmacy.

5.4.2.1.6 If the system detects no errors, it will compare the amount billed with the amount allowable for the prescribed drug and approve payment for the lower amount.

5.4.2.2 All completed claims are written in the POS adjudicated file. In addition, log files are updated to indicate whether claims were paid or rejected and if PRO DUR alert messages were sent to the pharmacy.

5.4.3 Claims Payment

5.4.3.1 All claims in the POS adjudicated file are considered paid. This means a second claim for the same member and drug will reject as a duplicate or for an early condition. Actual payment occurs after the weekly financial cycle, when claims from daily cycles are merged with POS claims. During the merge, batch claims are matched against POS adjudicated records to prevent duplicate payments.

5.4.4 Timely Filing

5.4.4.1 The POS-DUR program has a 100-day filing limit. This will ensure that the DUR program will have up-to-date and complete information by which to do the review. Claims may be submitted via POS for up to 120 days if the claim was rejected or only partially covered by the primary insurance.

5.5 Reserved

5.6 Reserved

5.7 Description of Messages

5.7.1 Drug Conflict - The code that is transmitted to the pharmacy to alert the pharmacist that the inbound drug claim conflicts with the member's therapy.

5.7.2 Codes and Messages - DUR messages are driven by the *conflict code*. In other words, the inbound claim is screened against active records in the member's historical drug profile. If drug interaction, prior adverse drug reaction, drug disease conflicts, duplicate therapy, or any of a whole host of therapeutic conflicts are detected, an alert message is transmitted back to the dispensing facility. A complete list of conflict codes is listed below:

Conflict Code	Definition(s)
DD	Drug-Drug Interaction
LD	Low Dose Alert
HD	High Dose Alert
ER	Overutilization
LR	Underutilization
DC	Inferred Drug Disease Precaution
PA	Drug Age Precaution
MC	Drug (Actual) Disease Precaution
PG	Drug Pregnancy Alert
TD	Therapeutic Duplication

5.7.3 Duplicate Therapy Module-A fundamental weakness of the NCPDP PRO-DUR template is the limit of three DUR messages per incoming claim. NCPDP minimizes this weakness via use of the DUR "overflow" indicator. If more than three messages exist for a given transmission, claims processors have been instructed to set their DUR Overflow indicators equal to "2". When

received by pharmacy software systems, this value will be interpreted to mean that additional DUR information exists for the last transmitted claim. The pharmacist then has the option of contacting the Help Desk to obtain this additional information.

5.7.4 Expected Behavior

5.7.4.1 The legislators responsible for drafting OBRA '90 mandated prospective DUR for each outpatient prescription dispensed to DMAP members. In addition, it is the expressed intent of these legislators to measure the effect of prospective DUR on member healthcare outcomes.

5.7.4.2 Delaware's PRO DUR system allows pharmacists to quickly document professional actions taken in support of their patients. This documentation can be communicated to us electronically in one of three ways:

5.7.4.2.1 It can be included with the standard payment claim

5.7.4.2.2 It can be included with the payment reversal

5.7.4.3 On all three of these vehicles, actions taken by the pharmacists are reported by using three two-character codes. The first two-character code is the CONFLICT Code, the second is the INTERVENTION Code and the third is the OUTCOME Code.

Conflict Code	Intervention Code	Outcome Code
XX	XX	XX

5.7.5 Pharmacist Intervention - Once the conflict has been determined the intervention the pharmacist has initiated should be recorded. The NCPDP approved prospective DUR intervention codes follow:

Intervention Code	Definition(s)
M0	Prescriber consulted
P0	Patient consulted
R0	Pharmacist Consulted Other Source

5.7.6 Outcome - After conflict and intervention have been identified, recording the OUTCOME of professional activity is all that remains. NCPDP approved OUTCOME codes are listed below:

Outcome Codes	Definition(s)
1A	Filled as is, false positive
1B	Filled Prescription as is
1C	Filled, with different dose
1D	Filled, with different directions

1E	Filled, with different drug
1F	Filled, with different quantity
1G	Filled, with prescriber approval

5.7.7 As mentioned earlier, Conflict, Intervention, and Outcome codes may be included on claims for payment, reversal transactions, and informational transactions. The presence of these three two-byte fields on an incoming claim will inform DMES that the dispensing pharmacist has already detected a conflict and has acted upon that information. In turn, DMES will adjudicate the claim. All DUR conflict messages will still be sent in response to the claim. The pharmacist may review the messages for additional information. If additional information is made available, the pharmacist may choose to review the claim and override the alert. Several case examples are found below:

5.7.7.1 Documentation of professional activity after receipt of prospective DUR message from claims processor:

5.7.7.1.1 Since Conflict, Intervention, and Outcome codes are available, pharmacists can document the thoughts and actions leading to the alert being overridden.

5.7.7.2 Documentation of professional activity prior to receipt of prospective message from claims processor:

5.7.7.2.1 The pharmacist (or the pharmacist's computer system) may detect inappropriate directions, drug allergies, or drug-medical condition conflicts without the benefit of the DMES ProDUR software. Quite often, these problems are resolved and dispensing then occurs. When the claim is transmitted, Conflict, Intervention, and Outcome codes should be included on the payable claim to document this activity.

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DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID & MEDICAL ASSISTANCE

Delaware Medical Assistance Program

Over-the Counter Products

6.0 Appendix A – Covered Over-the Counter Products

Current list of Rebate Eligible OTC products is located on the Pharmacy Corner Page: https://medicaid.dhss.delaware.gov/provider/Home/PharmacyCornerLanding/tabid/2096/Default.aspx.