



**MedStar Family
Choice**

ADMINISTRATIVE POLICY AND PROCEDURE

Policy #:	2001	
Subject:	Medical Drug Benefit Policy	
Section:	Medical Pharmacy	
Initial Effective Date:	July 16, 2026	
Revision Effective Date(s):		
Review Effective Date(s):		
Responsible Parties:	Medical Director, Health Plan Pharmacist	
Responsible Department(s):	Clinical Operations	
Regulatory References:	COMAR 10.67.04 Maryland Medicaid Managed Care Organization. Chapter 4 COMAR 10.67.06 Maryland Medicaid Managed Care Program: Benefits. Chapter 6 COMAR 10.09.03 Pharmacy Services Issue Date: September 14, 2018 Volume 45 • Issue 19 • Pages 869—870	
Approved:	Director of Pharmacy	Senior Medical Director (Chief Medical Officer)

Purpose: To establish medical necessity and utilization management requirements for medications administered under the medical benefit. This policy is intended to promote safe, clinically appropriate, evidence-based, and cost-effective use of provider-administered drugs while ensuring consistency in coverage determinations. Coverage decisions are based on FDA-approved labeling, nationally recognized clinical guidelines, peer-reviewed medical literature, and applicable health plan requirements.

Scope: This policy applies to all enrolled in MedStar Family Choice. In accordance with MedStar Family Choice's commitment to providing quality healthcare services, this policy establishes the requirements for the review, authorization, and management of medication covered under the Medical Benefit. It includes infused, injected, and physician-administered drugs billed through Buy & Bill arrangements in outpatient hospital, physician office, ambulatory infusion, home infusion settings and inpatient setting. The policy governs initial authorization requests, continuation of therapy reviews, site-of-care evaluations, biosimilar management, and medical necessity determinations. It does not apply to medications covered exclusively under the pharmacy benefit.

Policy: In accordance with the MedStar Family Choice Plan’s dedication to providing quality healthcare services, this policy allows eligible members to receive medically necessary medications covered under the Medical Benefit. Coverage decisions are based on medical necessities, clinical appropriateness, evidence-based guidelines, and applicable benefit requirements to support optimal health outcomes.

Definitions

Medical Reviewer	Medical Director or Health Plan Pharmacist
Medical Benefit Drug	A medication administered under the medical benefit, including infused, injected, or physician-administered drugs
Point of Service	The approved location or setting in which the medication is administered under the medical benefit
Site of Care	The clinically appropriate and cost-effective setting for administration of a medical benefit drug

Procedure:

A. Receipt of Request

1. Prior authorization requests for Medical Benefit drugs may be submitted by the prescribing provider, servicing provider, facility, or authorized representative.
2. Requests must include all required clinical documentation necessary to support medical necessity.
3. Requests are logged and assigned for review in accordance with applicable regulatory and organizational turnaround time requirements.

B. Eligibility Verification

1. Verify member eligibility and enrollment status.
2. Confirm the requested service is a covered Medical Benefit.
3. Confirm the member is enrolled in the applicable MedStar Family Choice.
4. Verify the servicing provider is participating or authorized, as applicable.

C. Clinical Documentation Review

1. The reviewer shall evaluate submitted clinical documentation, which may include:
 - Diagnosis and ICD-10 code
 - Clinical progress notes
 - Treatment plan
 - Previous treatment history and outcomes
 - Laboratory findings
 - Pathology reports
 - Imaging studies

- Medication dose and frequency
 - Requested duration of therapy
 - Point of service or site of administration
 - Member weight and/or body surface area, when applicable
2. Requests that do not include sufficient clinical documentation to support medical necessity and coverage requirements may be denied for insufficient information.

D. Medical Necessity Review

1. The reviewer shall determine whether the request meets applicable coverage requirements including:
 - Medical necessity
 - FDA-approved indications
 - Accepted standards of medical practice
 - Nationally recognized clinical guidelines
 - Drug-specific clinical criteria
 - Health plan coverage requirements
2. The reviewer shall assess:
 - Appropriateness of therapy
 - Clinical indication
 - Dose and frequency
 - Duration of treatment
 - Safety considerations
 - Monitoring requirements

E. Formulary and Biosimilar Review

1. The reviewer shall determine whether the requested medication is preferred, non-preferred, formulary, or non-formulary under the medical benefit.
2. When an FDA-approved preferred product or biosimilar has been designated by MedStar Family Choice, coverage may be limited to the preferred product or biosimilar.
3. Requests for non-preferred products or biosimilars must include documentation supporting medical necessity for the requested product.
4. Coverage of a non-formulary medication or non-preferred biosimilar may be considered when documentation demonstrates one or more of the following:
 - Failure of a preferred product or biosimilar
 - Contraindication to a preferred product or biosimilar
 - Intolerance or adverse reaction to a preferred product or biosimilar
 - Clinical circumstances supporting use of the requested product over the preferred alternative
5. The reviewer shall assess previous treatment history, clinical outcomes, and supporting documentation to determine whether formulary and biosimilar requirements have been met.
6. Requests that do not meet formulary or biosimilar requirements and do not include sufficient clinical justification may be denied.

7. MedStar Family Choice reserves the right to require use of preferred biosimilars when clinically appropriate and consistent with applicable coverage requirements.

F. Point of Service/ Site of Care Review

1. The reviewer shall evaluate the requested point of service for administration of the medication.
2. The point of service must be clinically appropriate, safe, and cost-effective based on the member's condition, the medication requested, monitoring requirements, and benefit rules.
3. Approved points of service may include:
 - Physician office
 - Ambulatory infusion center
 - Home infusion
 - Outpatient hospital department
4. The reviewer shall consider:
 - Drug-specific administration requirements
 - Patient safety and monitoring needs
 - History of adverse reactions or infusion-related complications
 - Availability of lower-cost clinically appropriate alternatives
 - Provider capability and setting suitability
 - Benefit design and applicable utilization management requirements
5. When multiple clinically appropriate settings are available, the plan may require administration at the most appropriate and cost-effective point of service.
6. A request for a higher-acuity or higher-cost point of service must include clinical justification. Examples of acceptable justification may include:
 - Need for intensive monitoring
 - History of severe infusion reaction
 - Drug-specific safety requirements
 - Lack of access to a lower-acuity setting
 - Other documented clinical circumstances supporting the requested setting
7. Requests for a point of service that is not medically necessary or not supported by clinical documentation may be denied or redirected to an alternative approved setting.

G. High-Cost Medication Review

1. High-cost medications may be subject to enhanced clinical and financial review. Requests involving significant financial impact, non-formulary products, exceptions to established criteria, or complex clinical circumstances shall be escalated to the Chief Medical Officer for review.
2. The Chief Medical Officer or designee shall serve as the final decision maker for escalated high-cost medication requests under the medical benefit.

H. Determination

Approval

1. Requests may be approved when:

- Coverage criteria are met
 - Required documentation has been received
 - Applicable utilization management requirements are satisfied
 - The requested or approved point of service is clinically appropriate
2. The authorization shall include, as applicable:
 - Medical necessity is established
 - Drug name
 - Dose
 - Frequency
 - Duration
 - Authorized units
 - Authorized point of service or site of care

Denial

1. Requests may be denied when:
 - Medical necessity is not established
 - Coverage criteria are not met
 - Insufficient documentation is provided
 - Requested use is not supported by applicable guidelines
 - A required preferred alternative has not been utilized
 - The requested point of service is not medically necessary or not supported by documentation

Medical benefit criteria can be found at www.medstarfamilychoice.com

I. Notification

1. Written notification shall be provided to the member and provider in accordance with regulatory requirements.
2. Determination notices shall include:
 - Approval or denial decision
 - Rationale for the decision
 - Authorization period, when applicable
 - Approved medication and point of service, when applicable
 - Appeal rights and instructions

J. Continuation of Therapy

1. For reauthorization requests, the reviewer shall assess:
 - Clinical response to treatment
 - Ongoing medical necessity
 - Treatment adherence
 - Adverse effects
 - Continued appropriateness of therapy
 - Continued appropriateness of the point of service
 - Documentation supporting continued benefit must be submitted for review.

Appendix:

High-Cost Medication List and Medical Drug Formulary List

High-Cost Medication List

Drug Name	HCP Code (if Applicable)
Abecma (idecabtagene vicleucel)	J9999
Actimmune (interferon gamma-1B)	J9216
Aetris (brentuximab vedotin)	J9042
Alhemo (concizumab)	J3590
Altuviiiio (antihemophili factor-recombinant)	J7214
Amondys 45 (casimersen)	J1426
Andembry (garadacimab)	J3590
Anktiva (inbakicept-pmln)	J9028
Aqneursa (levacetylleucine)	J8499
Avlayah (tividenofusp alfa-eknm)	J3590
Benefix (coagulation factor IX recombinant)	J7195
Blenrep (belantamab mafodotin-blmf)	J9053
Breyanzi (lisocabtagene maraleucel)	Q2054
Briumvi (Ublituximab)	J2329
Bylvay (odevixibat)	J8499
Carvykti (ciltacabtagene autoleucel)	Q2056
Cholbam (cholic acid)	J8499
Cinryze (C1 esterase inhibitor, human)	J0598
Ctexli (chenodiol)	J8499
Danyelza (naxitamab)	J9348

Dawnzera (donidalorsen)	J3490
Daybue (trofinetide)	J8499
Duvyzat (givinostat)	J8499
Elevidys (delandistrogene moxeparvovec-rokl)	J1413
Eloctate (antihemophilic factor VIII FC fusion protein recombinant)	J7205
Empaveli (pegcetacoplan)	J7799
Encelto (revakinagene tarorectcel-lwey)	J3403
Evkeeza (evinacumab)	J1305
Fabhalta (iptacopan)	J8499
Filsuvez (birch triterpenes)	J3490
Forzinity (elamipretide)	J3490
Gattex (Teduglutide)	J3490
Givlaari (Givosiran)	J0223
Haegarda (C1 esterase inhibitor, human)	J0599
Harliku (nitisinone)	J8499
Hemgenix (etranacogene dezaparvovec-drlb)	J1411
Hemlibra (etranacogene dezaparvovec)	J7170
Hympavzi (marstacimab- hncq)	J7172
Inlexzo (gemcitabine intravesical system)	J9183
Itvisma (onasemnogene abeparvovec-brve)	J3405
Jivi (antihemophilic factor- recombinant pegylated-aucl kit)	J7208
Joenja (leniolisib)	J8499
Juxtapid (lomitapide mesylate)	J8499
Kanuma (sbelipase alfa)	J2840
Kimmtrak (tebentafusp-tebn)	J9274
Krystexxa (pegloticase)	J2507
Lamzede (velmanase alfa- tycv)	J0217

Livmarli (maralixibat)	J8499
Miplyffa (arimoclomol)	J8499
Modeyso (dordaviprone)	J8999
Myalept (metreleptin)	J3490
Nexviazyme (avalglucosidase alfa-ngpt)	J0219
Novoseven (coagulation factor viia, recombinant)	J7189
Nulibry (fesdenopterin)	J3490
Olpruva (sodium phenylbutyrate)	J8499
Omisirge (omidubicel)	J3590
Orladeyo (berotralstat)	J8499
Oxlumo (lumasiran)	J0224
Pombiliti (cipaglucosidase alfa-atga)	J1203
Procysbi (cysteamine bitartrate)	J8499
Qfitlia (fitusiran)	J7174
Ravicti (glycerol phenylbutyrate)	J8499
Rethymic (allogeneic processed thymus tissue- agdc)	J3590
Revcovi (elapegademase- lvlr)	J3590
Rivfloza (nedosiran)	J3490
Roctavian (valoctocogene roxaparvovec-rvox)	J1412
Ryoncil (remestemcel-L- rknd)	J3402
Ryplazim (plasminogen, human-tvmh)	J2998
Scemblix (asciminib hydrochloride)	J8999
Sephience (sepiapterin)	J8499
Sohonos (palovarotene)	J8499
Soliris (eculizumab)	J1299
Spinraza (nusinersen)	J2326
Strensiq (asfotase alfa)	J3490
Takhzyro (lanadelumab-flyo)	J0593

Tryngolza (olezarsen sodium)	J3490
Veopoz (Pozelimab)	J9376
Viltepso (viltolarsen)	J1427
Vimizim (elosulfase alfa)	J1322
Vyjuvek (beremagene geperpavec-svdt)	J3401
Vykat XR (diazoxide choline extended-release)	J8499
Vyondys 53 (golodirsen)	J1429
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)***	J9334
Wainua (eplontersen)	J3490
Xenpozyme (olipudase alfa-rpcp)	J0218
Xolremdi (mavorixafor)	J8499
Xyntha (coagulation factor VIII- recombinant)	J7185
Yescarta (axicabtagene ciloleucel)	Q2041
Zokinvy (lonafarnib)	J8499
Zolgensma (onasemnogene abeparvovec-xioi)	J3399
Zycubo (copper histidinate)	J3490

Drug Name	J Code (if applicable)
Exondys 51 (eteplirsen)	J1428
Hepzato (melphalan)	J9248
Ogsiveo (nirogacestat)	J8999
Uplizna (inebilizumab-cdo)	J1823
Adstiladrin (darbepoetin alfa)	J9029
Adzynma (ADAMTS13)	J7171
Amtagvi (lifileucel)	J3590

Amvuttra (vutrisiran)	J0225
Blinicyto (blinatumomab)	J9039
Brineura (cerliponase alpha)	J0567
Cablivi (caplacizumab)	C9047
Cabometyx (cabozantinib)	J8999
Casgevy (exagamglogene autolemccl)	J3590
Cerezyme (imiglucerase/ glucocerebrosidase)	J1786
Columvi (glofitamab)	J9286
Crysvita (burosumab)	J0584
Elahere (mirvetuximab)	J9063
Elaprase (Idursulfase)	J1743
Elfabrio (pegunigalsidase alfa-iwxj)	J2508
Elrexfro (elranatamab)	J1323
Enspryng (satralilzumab)	J3590
Epkinly (epcoritamab-bysp)	J9321
Fyarro (nanoparticle albumin bound sirolimus)	J9331
Increlex (mecasermin)	J2170
Kebilidi (eladocagene exuparvovec- tmeq)	J3590

mifepristone (Korlym)	J8499
Lenmeldy (atidarsagene autotemcel)	J3590 C9399 J3490
Lumizyme (alglucosidase alfa)	J0220
Lunsumio (mosunetuzumab)	J9350
Luxturna (voretigene neparvovec)	J3398
Lyfgenia (lovotibeglogene autoemcel)	J3394
Mepsevii (vestronidase alpha)	J3397
Ojemda (tovorafenib)	J3490 C9399
Onpattro (patisiran)	J0222
Orfadin (nitisinone)	J8499
Orserdu (elacestrant)	J3490, J9999
Poteligeo (mogamulizumab)	J9204
Rydapt (midostaurin)	C9399 J3490
Rystiggo (rozanolixizumab)	J9333
Skysona (elivaldogene autotemcel)	J3590
Talvey (talquetamab)	J3055
Tecvayli (teclistamab)	J9380

Tepezza (teprotumumab)	J3241
Tevimbra (tislelizumab)	J9329
Tivdak (tisotumab vedotin)	J9273
Tziel (teplizumab)	J9381
Ultomiris (ravulizumab)	J1303
Unituxin (dinutuximab)	J9999
Xenopozyme (olipudase alfa-rpcp)	J0218
Yervoy (ipilimumab)	J9228
Zilbrysq (zilucoplan)	J3490, J3590, C9399
Zynlonta (loncastuximab tesirine- lpyl)	J9359
Zynteglo (betibeglogene autotemcel)	J3590
Jivi (factor VIII, recombinant human pegylated)	J7208
Xenpozyme (olipudase alfa- rpcp)	J0218

Medical Drug Formulary List

Neurology / MS / Migraine

J2350 – Ocrelizumab (Ocrevus)

J2323 – Natalizumab (Tysabri)

J3032 – Eptinezumab (Vyepti)

Autoimmune / Inflammatory / GI Biologics

J3380 – Vedolizumab (Entyvio)

J1745 – Infliximab (Remicade and biosimilars)

J2327 – Ustekinumab (Stelara)

J0490 – Belimumab (Benlysta)

J3262 – Tocilizumab (Actemra)

Immune Globulin (IVIG/SCIG)

J1561 – Immune globulin (IVIG), e.g., Gamunex-C, Gammaked

J1459 – Immune globulin (IVIG), e.g., Privigen

Ophthalmology (Anti-VEGF)

J0177 – Aflibercept (Eylea)

J0178 – Faricimab (Vabysmo)

J9035 – Bevacizumab (Avastin)

Other Specialty Injectables

J0585 – OnabotulinumtoxinA (Botox)

J0897 – Denosumab (Prolia, Xgeva)

J0741 – Anakinra (Kineret)

Oncology / Hematology / Supportive Care

J9021 – Atezolizumab (Tecentriq)

J9022 – Ado-trastuzumab emtansine (Kadcyla)

J9033 – Bendamustine (Bendeka, Treanda)

J9039 – Blinatumomab (Blincyto)

J9042 – Brentuximab vedotin (Adcetris)

J9047 – Carfilzomib (Kyprolis)

J9061 – Cisplatin

J9119 – Cemiplimab (Libtayo)

J9144 – Daratumumab hyaluronidase (Darzalex Faspro)

J9173 – Durvalumab (Imfinzi)

J9177 – Enfortumab vedotin (Padcev)
 J9202 – Goserelin (Zoladex)
 J9223 – Leuprolide acetate (Lupron Depot)
 J9228 – Ipilimumab (Yervoy)
 J9261 – Gemcitabine (Gemzar)
 J9264 – Paclitaxel protein-bound (Abraxane)
 J9271 – Pembrolizumab (Keytruda)
 J9272 – Nivolumab + relatlimab (Opdualag)
 J9298 – Nivolumab (Opdivo)
 J9299 – Nivolumab (Opdivo, alternative billing unit)
 J9303 – Panitumumab (Vectibix)
 J9308 – Ramucirumab (Cyramza)
 J9312 – Rituximab (Rituxan and biosimilars)
 J9316 – Rituximab + hyaluronidase (Rituxan Hycela)
 J9317 – Sacituzumab govitecan (Trodelvy)
 J9321 – Axicabtagene ciloleucel (Yescarta)
 J9347 – Tafasitamab (Monjuvi)
 J9352 – Trastuzumab (Herceptin and biosimilars)
 J9354 – Ado-trastuzumab emtansine (Kadcyla)
 J9358 – Fam-trastuzumab deruxtecan (Enhertu)

Other High-Cost / Supportive Agents

J0881 – Darbepoetin alfa (Aranesp)
 J0896 – Luspatercept (Reblozyl)
 J2506 – Pegfilgrastim (Neulasta and biosimilars)
 J2802 – Sutimlimab (Enjaymo)
 J2353 – Octreotide (Sandostatin LAR)

Summary of Changes:	7/26: • New Policy
----------------------------	---