RX.PA.014.MPC HIGH-COST LOW VOLUME DRUG RISK MITIGATION

The purpose of this policy is to define the prior authorization process for utilizing high-cost low volume (HCLV) medications.

The Maryland's Department of Health (the Department) has instituted a risk mitigation policy for high-cost low volume medications for both physician administered and retail pharmacy drugs. These medications are subject to the prior authorization process for MPC members, regardless of administration setting (inpatient and outpatient). The list of covered drugs is reviewed annually and subject to change.

Note: MPC does not conduct any retrospective review for these medications. All prior authorization requests must be approved by MPC prior to member administration. All additional supportive services required for the administration of these medication will be reviewed separately.

Drug Name	NDC Code	HCPCS Code (if Applicable)
Abecma (idecabtagene vicleucel)	59572-0515-01, 59572-0515-02, 59572-0515-03	J9999
Actimmune (interferon gamma-1B)	75987-0111-11, 75987-0111-10	J9216
Adcetris (brentuximab vedotin)	51144-0050-01	J9042
Alhemo (concizumab)	00169-2080-15, 00169-2084-15, 00169-2081-03	J3590
Altuviiio (antihemophili factor-recombinant)	71104-0978-01, 71104-0979-01, 71104-0981-01, 71104-0982-01, 71104-0983-01, 71104-0984-01	J7214
Amondys 45 (casimersen)	60923-0227-02	J1426
Andembry (garadacimab)	63833-0925-01	J3590
Anktiva (inbakicept-pmln)	81481-0803-01	J9028
Aqneursa (levacetylleucine)	83853-0101-01	J8499
Avlayah (tividenofusp alfa-eknm)	84976-0001-01	J3590
Benefix (coagulation factor IX recombinant)	58394-0633-03, 58394-0634-03, 58394-0635-03, 58394-0636-03, 58394-0637-03	J7195
Blenrep (belantamab mafodotin-blmf)	00173-0913-01	J9053
Breyanzi (lisocabtagene maraleucel)	73153-0900-01	Q2054
Bylvay (odevixibat)	15054-3301-01, 15054-3302-01, 15054-3303-01, 15054-3304-01	J8499

Carvykti (ciltacabtagene autoleucel)	57894-0111-01, 57894-0111-02	Q2056
Cholbam (cholic acid)	45043-0002-02**	J8499
Cinryze (C1 esterase inhibitor, human)	42227-0083-01	J0598
Ctexli (chenodiol)	79378-0310-90	J8499
Danyelza (naxitamab)	73042-0201-01	J9348
Dawnzera (donidalorsen)	71860-0103-01	J3490
Daybue (trofinetide)	63090-0660-01, 63090-0663-60; 63090-0664-60; 63090-0665-60	J8499
Duvyzat (givinostat)	11797-0110-01, 11797-0110-02	J8499
Elevidys (delandistrogene moxeparvovec-rokl)	60923-0503-12, 60923-0505-14, 60923-0506-15, 60923-0507-16, 60923-0508-17, 60923-0509-18, 60923-0510-19, 60923-0511-20, 60923-0512-21, 60923-0513-22, 60923-0514-23, 60923-0515-24, 60923-0516-25, 60923-0517-26, 60923-0518-27, 60923-0519-28, 60923-0520-29, 60923-0521-30, 60923-0522-31, 60923-0523-32, 60923-0524-33, 60923-0525-34, 60923-0526-35, 60923-0527-36, 60923-0528-37, 60923-0529-38, 60923-0530-39, 60923-0531-40, 60923-0532-41, 60923-0533-42, 60923-0534-43, 60923-0535-44, 60923-0536-45, 60923-0537-46, 60923-0538-47, 60923-0539-48, 60923-0540-49, 60923-0541-50, 60923-0542-51, 60923-0543-52, 60923-0544-53, 60923-0545-54, 60923-0546-55, 60923-0547-56, 60923-0548-57, 60923-0549-58, 60923-0550-59, 60923-0551-60, 60923-0552-61, 60923-0553-62, 60923-0554-63, 60923-0555-64, 60923-0556-65, 60923-0557-66, 60923-0558-67, 60923-0559-68, 60923-0560-69, 60923-0561-70	J1413
Eloctate (antihemophilic factor VIII FC fusion protein recombinant)	71104-0801-01, 71104-0802-01, 71104-0803-01, 71104-0805-01, 71104-0806-01;71104-0807-01 71104-0808-01, 71104-0809-01, 71104-0810-01	J7205
Empaveli (pegcetacoplan)	73606-0010-01	J7799
Encelto (revakinagene tarorectcel-lwey)	82958-0501-01	J3403
Evkeeza (evinacumab)	61755-0010-01, 61755-0013-01	J1305
Fabhalta (iptacopan)	00078-1189-20	J8499
Filsuvez (birch triterpenes)	10122-0310-01, 10122-0310-02	J3490
Forzinity (elamipretide)	72507-0800-04	J3490

Gattex (Teduglutide)	68875-0101-01, 68875-0102-01 , 68875-0103-01	J3490
Givlaari (Givosiran)	71336-1001-01	J0223
Haegarda (C1 esterase inhibitor, human)	63833-0828-02, 63833-0829-02	J0599
Harliku (nitisinone)	70709-0112-60	J8499
Hemgenix (etranacogene dezaparvovec-drlb)	00053-0099-01, 00053-0100-10, 00053-0110-11, 00053-0120-12, 00053-0130-13, 00053-0140-14, 00053-0150-15, 00053-0160-16, 00053-0170-17, 00053-0180-18, 00053-0190-19, 00053-0200-20, 00053-0210-21, 00053-0220-22, 00053-0230-23, 00053-0240-24, 00053-0250-25, 00053-0260-26, 00053-0270-27, 00053-0280-28, 00053-0290-29, 00053-0300-30, 00053-0310-31, 00053-0320-32, 00053-0330-33 , 00053-0340-34, 00053-0350-35, 00053-0360-36, 00053-0370-37, 00053-0380-38, 00053-0390-39, 00053-0400-40, 00053-0410-41, 00053-0420-42, 00053-0430-43, 00053-0440-44, 00053-0450-45, 00053-0460-46, 00053-0470-47, 00053-0480-48	J1411
Hemlibra (etranacogene dezaparvovec)	50242-0920-01; 50242-0921-01; 50242-0922-01; 50242-0923-01; 50242-0927-01; 50242-0930-01	J7170
Hympavzi (marstacimab-hncq)	00069-2151-01	J7172
Inlexzo (gemcitabine intravesical system)	57894-0225-01	J9183
Itvisma (onasemnogene abeparvovec-brve)	71894-0200-02	J3405
Jivi (antihemophilic factor-recombinant pegylated-aucl kit)	00026-3942-25; 00026-3944-25; 00026-3946-25; 00026-3948-25; 00026-3950-50	J7208
Joenja (leniolisib)	71274-0170-60	J8499
Juxtapid (lomitapide mesylate)	10122-0402-28, 10122-0405-28, 10122-0410-28, 10122-0420-28, 10122-0430-28	J8499
Kanuma (sbelipase alfa)	25682-0007-01	J2840
Kimmtrak (tebentafusp-tebn)	80446-0401-01	J9274
Krystexxa (pegloticase)	75987-0080-10, 75987-0058-01	J2507
Lamzede (velmanase alfa-tycv)	10122-0180-01, 10122-0180-02	J0217
Livmarli (maralixibat)	79378-0110-01, 79378-0111-01, 79378-0210-30, 79378-0215-30, 79378-0220-30, 79378-0230-30	J8499

Miplyffa (arimoclomol)	72542-0124-01, 72542-0147-01, 72542-0162-01, 72542-0193-01	J8499
Modeyso (dordaviprone)	68727-0250-01	J8999
Myalept (metreleptin)	10122-0210-01, 10122-0210-02, 76431-0210-01****	J3490
Nexviazyme (avalglucosidase alfa-ngpt)	58468-0426-01	J0219
Novoseven (coagulation factor viia, recombinant)	00169-7201-01, 00169-7202-01, 00169-7205-01, 00169-7208-01, 00169-7211-11, 00169-7212-11 , 00169-7215-11, 00169-7218-11	J7189
Nulibry (fesdenopterin)	42358-0295-01	J3490
Olpruva (sodium phenylbutyrate)	72542-0200-02, 72542-0200-09, 72542-0300-02, 72542-0300-09, 72542-0400-02, 72542-0400-18, 72542-0500-02, 72542-0500-18, 72542-0600-02, 72542-0600-18, 72542-0667-02, 72542-0667-18	J8499
Omisirge (omidubicel)	73441-0800-04	J3590
Orladeyo (berotralstat)	72769-0101-01, 72769-0102-01, 72769-0111-02, 72769-0112-02, 72769-0113-02, 72769-0114-02	J8499
Oxlumo (lumasiran)	71336-1002-01	J0224
Pombiliti (cipaglucosidase alfa-atga)	71904-0200-01	J1203
Procysbi (cysteamine bitartrate)	75987-0101-08	J8499
Qfitlia (fitusiran)	58468-0348-01**	J7174
Ravicti (glycerol phenylbutyrate)	75987-0050-06, 49884-0264-95, 70748-0425-01	J8499
Rethymic (allogeneic processed thymus tissue-agdc)	72359-0001-01	J3590
Revcovi (elapegademase-lvlr)	10122-0502-01	J3590
Rivfloza (nedosiran)	00169-5306-10, 00169-5307-08, 00169-5308-01	J3490
Roctavian (valoctocogene roxaparvovec-rvox)	68135-0927-01, 68135-0927-48	J1412
Ryoncil (remestemcel-L-rknd)	73648-0111-01, 73648-0112-02, 73648-0113-03, 73648-0114-01, 73648-0115-02, 73648-0116-03, 73648-0117-04, 73648-0118-02, 73648-0119-03, 73648-0120-04, 73648-0121-05, 73648-0122-03	J3402
Ryplazim (plasminogen, human-tvmh)	70573-0099-01, 70573-0099-02	J2998

Scemblix (asciminib hydrochloride)	00078-1196-20**	J8999
Sephience (sepiapterin)	52856-0201-03, 52856-0301-03	J8499
Sohonos (palovarotene)	15054-0010-01, 15054-0015-01, 15054-0025-01, 15054-0050-01, 15054-0100-01	J8499
Soliris (eculizumab)	25682-0001-01	J1299
Spinraza (nusinersen)	64406-0058-01, 64406-0036-01, 64406-0037-01	J2326
Strensiq (asfotase alfa)	25682-0016-12, 25682-0019-12**	J3490
Takhzyro (lanadelumab-flyo)	47783-0646-01**	J0593
Tryngolza (olezarsen sodium)	71860-0101-01	J3490
Veopoz (Pozelimab)	61755-0014-01	J9376
Viltepso (viltolarsen)	73292-0011-01	J1427
Vimizim (elosulfase alfa)	68135-0100-01	J1322
Vyjuvek (beremagene geperpavec-svdt)	82194-0510-02	J3401
Vykat XR (diazoxide choline extended-release)	83860-0075-01, 83860-0150-01**	J8499
Vyondys 53 (golodirsen)	60923-0465-02	J1429
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)***	73475-3102-03; 73475-1221-01; 73475-1221-04***	J9334
Wainua (eplontersen)	00310-9400-01	J3490
Xenpozyme (olipudase alfa-rpcp)	58468-0050-01**	J0218
Xolremdi (mavorixafor)	83296-0100-12**	J8499
Xyntha (coagultion factor VIII- recombinant)	58394-0016-03,58394-0022-03, 58394-0023-03, 58394-0024-03, 58394-0025-03, 58394-0012-01, 58394-0013-01, 58394-0014-01, 58394-0015-01	J7185
Yescarta (axicabtagene ciloleucel)	71287-0119-01, 71287-0119-02	Q2041
Zokinvy (lonafarnib)	42358-0450-30, 42358-0475-30, 73079-0050-30****, 73079-0075-30****	J8499

Zolgensma (onasemnogene abeparvovec-xioi)	71894-0120-02, 71894-0121-03, 71894-0122-03, 71894-0123-03, 71894-0124-04, 71894-0125-04, 71894-0126-04, 71894-0127-05, 71894-0128-05, 71894-0129-05, 71894-0130-06, 71894-0131-06, 71894-0132-06, 71894-0133-07, 71894-0134-07, 71894-0135-07, 71894-0136-08, 71894-0137-08, 71894-0138-08, 71894-0139-09, 71894-0140-09, 71894-0141-09, 71894-0142-10, 71894-0143-10, 71894-0144-10, 718940145-11, 71894-0146-11, 71894-0147-11, 71894-0148-12, 71894-0149-12, 71894-0150-12, 71894-0151-13, 71894-0152-13, 71894-0153-13, 71894-0154-14, 71894-0155-14, 71894-0156-14	J3399
Zycubo (copper histidinate)	42358-0329-01	J3490

MDH reserves the right to add and remove NDC numbers at their discretion.
*On demand bleeding products for hemophilia are not covered as part of the HCLV drug list policy
**Other NDCs are not covered as dosing using these package sizes would not meet the HCLV threshold of >500K annually
***Covered only when used for chronic inflammatory demyelinating polyneuropathy (CIDP)
****NDCs covered until CMS term date of 1/31/28

MPC INPATIENT HIGH-COST LOW VOLUME DRUG RISK MITIGATION

This policy covers inpatient drugs with an expected annual cost over $1,000,000, beginning with calendar year 2026. The list of drugs is subject to change during the year if a new drug received FDA approval and is a covered Medicaid service with an expected annual cost over $1,000,000.

Note: MPC does not conduct any retrospective review for these medications. All prior authorization requests must be approved by MPC prior to member administration. All additional supportive services required for the administration of these medications will be reviewed separately.

Drug Name	NDC Code	HCPCS Code (if applicable)
Lenmeldy	83222-0200-01	J3391
Kebilidi	52856-0601-01	
Skysona	73554-2111-01	
Zynteglo	73554-3111-01	J3393

REVIEW HISTORY

DESCRIPTION OF REVIEW/ REVISION	DATE APPROVED
Selected Revision *Addition and removal of approved MDH medications, NDC codes, J codes*	*06/2026*
Annual review	*02/2026*
Selected Revision *Addition and removal of approved MDH medications, NDC codes, J codes* *Addition of Inpatient High Cost Low Volume medication list*	*1/2026*
Selected Revision *Addition and removal of approved MDH medications, NDC codes, J codes*	*05/2025*
Annual review	*02/2025*
Selected Revision *Addition and removal of approved MDH medications, NDC codes, J codes*	*01/2025*
Selected Revision *Addition and removal of approved MDH medications, NDC codes, J codes* *Addition of language to address authorization requirements basedon infusion setting*	*11/2024*
Annual review	*02/2024*
Selected Revision *Addition and removal of approved MDH medications, NDCcodes, J codes*	*01/2024*
Selected Revision *Addition of newly approved MDH medications, NDC codes, J codes*	*08/2023*
Annual review and inclusion of new medications highlighted in red	*02/2023*
Annual review	*02/2022*
New Policy	*02/2021*