



POLICY NUMBER: RX.PA.014.MPC

REVISION DATE: 01/2026

PAGE NUMBER: 1 OF 8

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, 71104-0980-01, 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-pmIn)	81481-0803-01	J9028
Aqneursa (levacetylleucine)	83853-0101-01	J8499
Benefix (coagulation factor IX recombinant)	58394-0633-03, 58394-0634-03, 58394-0635-03, 58394-0636-03, 58394-0637-03	J7195
Beqvez (fidanacogene)	00069-0422-01, 00069-2004-04,	J1414

Drug Name	NDC Code	HCPCS Code (if Applicable)
elaparvovec-dzkt)	00069-2004-14, 00069-2005-05, 00069-2005-15, 00069-2006-06, 00069-2006-16, 00069-2007-07, 00069-2007-17	
Breyanzi (lisocabtagene maraleucel)	73153-0900-01	Q2054
Bylvay (odevixibat)	74528-0040-01, 74528-0120-01	J8499
Carvykti (ciltacabtagene autoleucel)	57894-0111-01, 57894-0111-02	J9999, Q2056
Chenodal (chenodiol)	68974-0876-40	J8499
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
Daybue (trofinetide)	63090-0660-01	J8499
Duvyzat (givinostat)	11797-0110-01, 11797-0110-02	J8499
Elevidys (delandistrogene moxeparvovec-rokl)	60923-0501-10 , 60923-0502-11 , 60923-0503-12, 60923-0504- 13, 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,	J1413

Drug Name	NDC Code	HCP Code (if Applicable)
	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	
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	J3590
Evkeeza (evinacumab)	61755-0010-01, 61755-0013-01	J1305
Fabhalta (iptacopan)	00078-1189-20	J8499
Filsuvez (birch triterpenes)	10122-0310-02, 76431-0310-01	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
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-	J1411

Drug Name	NDC Code	HCPCS Code (if Applicable)
	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	
Hemlibra (etranacogene dezaparvovec)	50242-0920-01; 50242-0921-01; 50242-0922-01; 50242-0923-01; 50242-0927-01; 50242-0930-01	J7170
Hypavzi (marstacimab- hncq)	00069-2151-01	J7172
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)	10122-0405-28, 10122-0410-28, 10122-0420-28, 10122-0430-28, 76431-0105-01, 76431-0110-01, 76431-0120-01, 76431-0130-01	J8499
Kanuma (sbelipase alfa)	25682-0007-01	J2840
Kimmtrak (tebentafusp- tebn)	80446-0401-01	J9274
Krystexxa (pegloticase)	75987-0080-10	J2507
Lamzedo (velmanase alfa- tycv)	10122-0180-02, 10122-0180- 05, 10122-0180-10	J0217
Livmarli (maralixibat)	79378-0110-01	J8499
Miplyffa (arimoclomol)	72542-0124-01, 72542-0147-01, 72542-0162-01, 72542-0193-01	J8499
Myalept (metreleptin)	76431-0210-01	J3490
Nexvazyme (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)	73129-0001-01	J3490
Olpruva (sodium phenylbutyrate)	72542-0002-01, 72542-0200-02, 72542-0200-09, 72542-0003-01,	J8499

Drug Name	NDC Code	HCPCS Code (if Applicable)
	72542-0300-02, 72542-0300-09, 72542-0400-02, 72542-0400-18, 72542-0500-02, 72542-0500-18, 72542-0600-02, 72542-0600-18, 72542-0367-01, 72542-0667-02, 72542-0667-18	
Omisirge (omidubicel)	73441-0800-04	J3590
Orladeyo (berotralstat)	72769-0101-01, 72769-0102-01	J8499
Oxlumo (lumasiran)	71336-1002-01	J0224
Pombiliti (cipaglucosidase alfa-atga)	71904-0200-01, 71904-0200-02, 71904-0200-03	J1203
Procysbi (cysteamine bitartrate)	75987-0101-08	J8499
Qfitlia (fitusiran)	58468-0348-01**	J3490
Ravicti (glycerol phenylbutyrate)	75987-0050-06	J8499
Rethymic (allogeneic processed thymus tissue- agdc)	72359-0001-01	J3590
Revcovi (elapegademase- lvlr)	57665-0002-01	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	J3590
Ryplazim (plasminogen, human-tvmh)	70573-0099-01, 70573-0099-02	J2998
Scemblix (asciminib hydrochloride)	00078-1196-20**	J8999
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	J2326
Strensiq (asfotase alfa)	25682-0016-12, 25682-0019-	J3490

Drug Name	NDC Code	HCPSC Code (if Applicable)
	12**	
Takhzyro (lanadelumab-flyo)	47783-0644-01; 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
Vyondys 53 (golodirsen)	60923-0465-02	J1429
Vykat XR (diazoxide choline extended-release)	83860-0075-01, 83860-0150-01**	J8499
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 (coagulation 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)	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,	J3399

Drug Name	NDC Code	HCPCS Code (if Applicable)
	71894-0141-09; 71894-0156-14; 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	

*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)

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 medication will be reviewed separately.

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

REVIEW HISTORY

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