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)
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	J7199
Amondys 45 (casimersen)	60923-0227-02	J1426
Anktiva (inbakicept-pmln)	81481-0803-01	J9399
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 elaparvovec-dzkt)	00069-0422-01, 00069-2004-04, 00069-2004-14, 00069-2005-05, 00069-2005-15, 00069-2006-06, 00069-2006-16, 00069-2007-07, 00069-2017	J3590
Bylvay (odevixibat)	74528-0040-01, 74528-0120-01	J8499

Cinryze (C1 esterase inhibitor, human)	42227-0081-05	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, 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	J3490, J3590
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
Encelto (revakinagene tarorectcel-lwey)	82958-0501-01	J3590
Evkeeza (evinacumab)	61755-0010-01, 61755-0013-01	J1305
Fabhalta (iptacopan)	00078-1189-20	J8499

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, 00053-0370-37, 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	J3590
Jivi (antihemophilic factor-recombinant pegylated-aucl kit)	00026-3942-25; 00026-3944-25; 00026-3946-25; 00026-3948-25	J7208
Joenja (leniolisib)	71274-0170-60	J8499
Kimmtrak (tebentafusp-tebn)	80446-0401-01	J9274
Krystexxa (pegloticase)	75987-0080-10	J2507
Lamzede (velmanase alfa-tycv)	10122-0180-02, 10122-0180-05,10122-0180-10	J3490, J3590
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, J3590

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)	73129-0001-01	J3490
Olpruva (sodium phenylbutyrate)	72542-0002-01, 72542-0200-02, 72542-0200-09, 72542-0003-01, 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	J8499
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, J3490
Rivfloza (nedosiran)	00169-5306-10, 00169-5307-08, 00169-5308-01	J3490
Roctavian (valoctocogene roxaparvovec-rvox)	68135-0927-01, 68135-0927-48	J3490, J3590
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
Sohonos (palovarotene)	15054-0010-01, 15054-0015-01, 15054-0025-01, 15054-0050-01, 15054-0100-01	J8499
Soliris (eculizumab)	25682-0001-01	J1300
Spinraza (nusinersen)	64406-0058-01	J2326

Takhzyro (lanadelumab-flyo)	47783-0644-01	J0593
Tryngolza (olezarsen sodium)	71860-0101-01	J3490
Veopoz (Pozelimab)	61755-0014-01	J3590
Viltepso (viltolarsen)	73292-0011-01	J1427
Vimizim (elosulfase alfa)	68135-0100-01	J1322
Vyjuvek (beremagene geperpavec-svdt)	82194-0510-02	J3590
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	J9334
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
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	J3399

***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**

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
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 based on infusion setting*	*11/2024*
Annual review	*02/2024*
Selected Revision *Addition and removal of approved MDH medications, NDC codes, 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*