

09-J4000-30

Original Effective Date: 07/01/22

Reviewed: 06/11/25

Revised: 04/15/26

Subject: New-To-Market Program for Medical Benefit Medications

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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DESCRIPTION:

The New-To-Market Program for Medical Benefit Medications affords Florida Blue the ability to review, evaluate, assess coverage status, and develop programs for newly marketed, medications (including biologics and biosimilars, radiopharmaceuticals, and gene and cell therapies) reimbursed under the member's medical benefit prior to coverage. These are most often provider administered medications, but not always. Certain medical benefit medications will not be covered until Florida Blue's committees have had an opportunity to review the medication and determine whether it is medically necessary, and, if so, if any utilization management program will apply based on safety, efficacy, and the availability of other products within that class of medications.

POSITION STATEMENT:

This policy may apply to newly marketed medications (including biologics and biosimilars, radiopharmaceuticals, and gene and cell therapies) that are:

- Approved by the U.S. Food and Drug Administration (FDA), and
- Administered by a healthcare provider, and/or
- Reimbursed under the member's medical benefit.

New medications that are identified as being subject to this policy will be placed on the "New-To-Market Program for Medical Benefit Medications Drug List".

In accordance with the member's health plan benefits (i.e., Benefit Booklet's Definitions, What is Covered, and What is Not Covered sections), any medications identified on the New-To-Market Program for Medical Benefit Medications Drug List **will be considered a benefit exclusion (i.e., a non-covered/non-reimbursable service)**.

Pre-service reviews and claims submitted for medications identified on New-To-Market Program for Medical Benefit Medications Drug List will be denied as a non-covered benefit.

Medications identified on the New-To-Market Program for Medical Benefit Medications Drug List will be subject to this policy until such time that Florida Blue's committees complete their evaluations and a

Medical Coverage Guideline (MCG) defining coverage (or lack of coverage) and the associated medically necessary criteria are active.

New-To-Market Program for Medical Benefit Medications Drug List

Medication Name	Initial Unclassified HCPCS Code	Date Added
Avlayah (tvidenofusp alfa-eknm) intravenous infusion	J3590	04/03/26
Itvisma (onasemnogene abeparvovec-brve) intrathecal injection	J3590 (assigned code C9309, for hospital outpatient use only, on 04/01/26)	11/26/25
Loargys (pegzilarginase-nbln) injection	J3590	04/01/26
Vykoura (leucovorin calcium) injection	J9999	02/20/26
Zevaskyn (prademagene zamikeracel) gene-modified cellular sheets	J3590 (assigned code J3389 on 01/01/26)	08/25/25

BILLING/CODING INFORMATION:

HCPCS Coding

A9699	Radiopharmaceutical, therapeutic, not otherwise classified
J0799	FDA approved prescription drug, only for use as HIV pre-exposure prophylaxis (not for use as treatment of HIV), not otherwise classified
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1599	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg
J3490	Unclassified drugs
J3590	Unclassified biologics
J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified [only when billed under the medical benefit]
J9999	Not otherwise classified, antineoplastic drugs

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): FEP is excluded from this program; follow FEP guidelines.

State Account Organization (SAO): SAO is excluded from this program; follow SAO guidelines.

Medicare Advantage: Medicare Advantage is excluded from this program.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

REFERENCES:

1. Avlayah (tividenofusp alfa-eknm for injection, for intravenous use) [package insert]. Denali Therapeutics Inc. South San Francisco, CA: March 2026. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761485s000lbl.pdf
2. Itvisma (onasemnogene abeparvovec-brve suspension, for intrathecal injection) [package insert]. Novartis Gene Therapies, Inc. Bannockburn, IL; November 2025. Available at: <https://www.fda.gov/media/189857/download?attachment>
3. Loargys (pegzilarginase-nbln injection, for intravenous or subcutaneous use) [package insert]. Immedica Pharma US Inc. Chicago, IL; February 2026. Available at: <https://www.immedicaus.com/sites/default/files/pr/highlights-of-prescribing-information-loargys.pdf>
4. Vykoura (leucovorin calcium injection, for intravenous or intramuscular use) [package insert]. Avyxa Pharma, LLC. New Jersey 07054, USA: February 2026. Available at: www.accessdata.fda.gov/drugsatfda_docs/label/2026/220406s000lbl.pdf
5. Zevaskyn (prademagene zamikeracel, gene-modified cellular sheets for topical use) [package insert]. Abeona Therapeutics Inc. Cleveland, OH: April 2025. Available at: <https://www.fda.gov/media/186511/download?attachment>

COMMITTEE AP PROVAL:

This policy was approved by the Florida Blue Pharmacy Policy Committee on 07/09/25.

GUIDELINE UPDATE INFORMATION:

07/01/22	New Medical Coverage Guideline.
08/22/22	Addition of Zynteglo (betibeglogene autotemcel) to the drug list.
09/15/22	Additions of Rolvedon (eflapegrastim-xnst), Spevigo (spesolimab), Stimufend (pegfilgrastim-fpgk), and Xenpozyme (olipudase alfa) to the drug list.
11/15/22	Removals of Spevigo (spesolimab), Xenpozyme (olipudase alfa), and Zynteglo (betibeglogene autotemcel) from the drug list.
11/23/22	Additions of Hemgenix (etranacogene dezaparvovec) and Tzield (teplizumab-mzvw) to the drug list.
01/01/23	Removals of Rolvedon (eflapegrastim-xnst) and Stimufend (pegfilgrastim-fpgk) from the drug list.
01/10/23	Addition of Leqembi (lecanemab-irmb) to the drug list.
02/15/23	Removal of Tzield (teplizumab-mzvw) from the drug list.
03/15/23	Removals of Leqembi (lecanemab-irmb) and Hemgenix (etranacogene dezaparvovec) from the drug list.
07/15/23	Review of guideline with no changes. Additions of Lantidra (donislecel-jujn) and Roctavian (valoctocogene roxaparvovec-rvox) to the drug list.
07/19/23	Addition of Elevidys (delandistrogene moxeparvovec-rokl) to the drug list.
08/25/23	Addition of Eylea HD (aflibercept 8 mg) to the drug list.
09/15/23	Removal of Lantidra (donislecel-jujn) from the drug list.
10/05/23	Additions of Pombiliti (cipaglugosidase alfa-atga) and Rivfloza (nedosiran) to the drug list.
11/03/23	Addition of Omvoh (mirikizumab-mrkz) to the drug list.
12/15/23	Additions of Casgevy (exagamglogene autotemcel) and Lyfgenia (lovotibeglogene autotemcel) to the drug list.
01/01/24	Revision: Added specific HCPCS codes for Elevidys, Eylea HD, and Roctavian.
01/15/24	Removed Eylea HD (aflibercept 8 mg) from the drug list.
04/01/24	Removed Casgevy (exagamglogene autotemcel), Lyfgenia (lovotibeglogene autotemcel),

	Omvo (mirikizumab-mrkz), Pombiliti (cipaglucosidase alfa-atga), Rivfloza (nedosiran), and Roctavian (valoctocogene roxaparvovec-rvox) from the drug list.
04/02/24	Addition of Winrevair (sotatercept-csrk) to the drug list.
05/01/24	Addition of Beqvez (fidanacogene elaparvovec-dzkt) to the drug list.
06/15/24	Removed Elevidys (delandistrogene moxeparvovec-rokl) from the drug list.
07/01/24	Removed Winrevair (sotatercept-csrk) from the drug list.
07/15/24	Additions of Kisunla (donanemab-azbt) and Piasky (crovalimab-akkz) to the drug list.
09/15/24	Review and revision of guideline with updates to the description section, position statement, and billing/coding. Expanded the scope of the program to include any medical benefit medication. Removed Beqvez (fidanacogene elaparvovec-dzkt), Kisunla (donanemab-azbt) and Piasky (crovalimab-akkz) from the drug list.
10/15/24	Addition of Posfrea (palonosetron) injection to the drug list.
10/30/24	Addition of Pavblu (afibercept-ayyh) injection to the drug list.
11/15/24	Addition of Kebilidi (eladocagene exuparvovec-tneq) and Vyalev (foscarbidopa/foslevodopa) to the drug list.
01/01/25	Additions of Wezlana (ustekinumab-auub) SC injection and IV infusion to the drug list.
01/15/25	Removed Posfrea (palonosetron) and Kebilidi (eladocagene exuparvovec-tneq) from the drug list.
02/17/25	Additions of Otulfi (ustekinumab-aauz) and Pyzchiva (ustekinumab-ttwe) SC injections and IV infusions to the drug list.
04/01/25	Revision: Added Bkerv (eculizumab-aeab) IV infusion and Epysqli (eculizumab-aagh) IV infusion to the drug list. Removed Vyalev (foscarbidopa/foslevodopa) injection from the drug list. Added HCPCS code Q9999 for Otulfi and code Q5147 for Pavblu.
04/15/25	Removed Pavblu (afibercept-ayyh) injection from the drug list.
05/01/25	Additions of Boruzu (bortezomib injection) and Imuldosa (ustekinumab-srlf) SC injections and IV infusions to the drug list.
05/15/25	Addition of Tepylute (thiotepa) injection for intravenous use to the drug list.
05/20/25	Addition of Imaavy (nipocalimab-aahu) IV infusion to the drug list.
06/15/25	Removed Bkerv (eculizumab-aeab) IV infusion and Epysqli (eculizumab-aagh) IV infusion from the drug list.
07/01/25	Added Bomytra (denosumab-bnht) and Conexence (denosumab-bnht) SC injections, and removed Wezlana (ustekinumab-auub), Otulfi (ustekinumab-aauz), Pyzchiva (ustekinumab-ttwe) and Imuldosa (ustekinumab-srlf) SC injections and IV infusions from the drug list. Added HCPCS code for Tepylute.
07/08/25	Additions of Yeztugo SC injection and tablets to the drug list.
07/28/25	Addition of Avgemsi (gemcitabine) IV infusion to the drug list.
08/15/25	Review and revision of guidelines. Added clarifying language that biologics and biosimilars, radiopharmaceuticals, and gene and cell therapies are encompassed under the term "medications".
08/25/25	Additions of Papzimeos (zopapogene imadenovec-drba) SC injection and Zevaskyn (prademagene zamikeracel) gene-modified cellular sheets to the drug list.
09/15/25	Additions of Kyxata (carboplatin) IV infusion and Jobevne (bevacizumab-nwgd) IV infusion to the drug list.
10/01/25	Removed Yeztugo SC injection and tablets from the drug list. Added HCPCS code C9305 for Imaavy and code Q5158 for Bomytra/Conexence.
10/10/25	Addition of Avtozma (tocilizumab-anoh) IV infusion to the drug list.
10/15/25	Removed Boruzu (bortezomib) injection, Tepylute (thiotepa) injection, Imaavy (nipocalimab-aahu) IV infusion, and Bomytra (denosumab-bnht) and Conexence (denosumab-bnht) SC injections from the drug list.
11/15/25	Removed Jobevne (bevacizumab-nwgd), Kyxata (carboplatin), and Papzimeos (zopapogene imadenovec-drba) from the drug list. Added Starjemza (ustekinumab-hmny) IV infusion and SC injection to the drug list.
11/26/25	Addition of Itvisma (onasemnogene abeparvovec-brve) intrathecal injection to the drug list.

12/15/25	Addition of Waskyra (etuvetidigene autotemcel) IV infusion to the drug list.
01/01/26	Added Exdensur (depemokimab-ulaa) SC injection, Rybrevant Faspro (amivantamab and hyaluronidase-lpuj) SC injection, and Vabrinty (leuprolide acetate extended release) SC injection to the drug list. Removed Avgemsi (gemcitabine) IV infusion, Avtozma (tocilizumab-anoh) IV infusion, and Starjemza (ustekinumab-hmny) IV infusion and SC injection from the drug list. Added HCPCS code J3389 for Zevaskyn.
02/20/26	Addition of Vykoura (leucovorin calcium) injection to the drug list.
03/09/26	Addition of Qivigy (immune globulin intravenous, human-kthm) 10% solution to the drug list.
03/15/26	Removed Exdensur (depemokimab-ulaa) subcutaneous injection, Rybrevant Faspro (amivantamab and hyaluronidase-lpuj) subcutaneous injection, and Waskyra (etuvetidigene autotemcel) IV infusion from the drug list.
04/01/26	Addition of Loargys (pegzilarginase-nbln) injection to the drug list. Added code C9309 for Itvisma.
04/03/26	Addition of Avlayah (tividienofusp alfa-eknm) intravenous infusion to the drug list.
04/15/26	Removed Qivigy (immune globulin intravenous, human-kthm) 10% solution and Vabrinty (leuprolide acetate extended release) SC injection from the drug list.