

09-J4000-30

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## 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 |
|--|--|------------|
| Boruzu (bortezomib) SC injection and IV infusion                 | J9054 (entered market with an assigned code) | 05/01/25   |
| Tepylute (thiotepa) IV infusion                                  | J9999 (updated to J9341 on 07/01/25)         | 05/15/25   |
| Imaavy (nipocalimab-aahu) IV infusion                            | J3590  | 05/20/25   |
| Bomyntra (denosumab-bnht) SC injection                           | J3590  | 07/01/25   |
| Conexence (denosumab-bnht) SC injection                          | J3590  | 07/01/25   |
| Yeztugo (lenacapavir) SC injection                               | J0799  | 07/08/25   |
| Yeztugo (lenacapavir) tablets                                    | J0799  | 07/08/25   |
| Avgemsi (gemcitabine) IV infusion                                | J9999  | 07/28/25   |
| Papzimeos (zopapogene imadenovec-drba) SC injection              | J3590  | 08/25/25   |
| Zevaskyn (prademagene zamikeracel) gene-modified cellular sheets | J3590  | 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. Avgemsi (gemcitabine injection, solution) [package insert]. Avyxa Pharma, LLC. New Jersey, USA: July 2025. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e11eeff7-bcaf-4bf1-8da8-88138e01af84>
2. Bomynta (denosumab-bnht injection, for subcutaneous use) [package insert]. Fresenius Kabi USA, LLC. Lake Zurich, IL: March 2025. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2025/761398Orig1s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761398Orig1s000lbl.pdf).
3. Boruzu (bortezomib injection) [package insert]. Amneal Pharmaceuticals LLC. Bridgewater, NJ: September 2024. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b92628dd-fa09-4c3a-b6a3-66426025807c>.
4. Conexence (denosumab-bnht injection, for subcutaneous use) [package insert]. Fresenius Kabi USA, LLC. Lake Zurich, IL: March 2025. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2025/761398Orig1s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761398Orig1s000lbl.pdf).
5. Imaavy (nipocalimab-aahu injection, for intravenous use) [package insert]. Janssen Biotech, Inc. Horsham, PA: April 2025. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2025/761430s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761430s000lbl.pdf).
6. Papzimeos (zopapogene imadenovec-drba, suspension for subcutaneous injection) [package insert]. Precigen, Inc. Germantown, MD: August 2025. Available at: <https://precigen.com/papzimeos-prescribing-information.pdf>.

7. Tepylute (thiotepa injection, for intravenous use) [package insert]. Shorla Oncology Inc. Cambridge, MA: February 2025. Available at:  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2025/216984Orig1s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/216984Orig1s001lbl.pdf).
8. Yeztugo (lenacapavir tablets for oral use and injection for subcutaneous use) [package insert]. Gilead Sciences, Inc. Foster City, CA: June 2025. Available at:  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2025/220018s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/220018s000lbl.pdf).
9. 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-mzwv) 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-mzwv) 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 (cipaglucosidase 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 (exagamlogene 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 (exagamlogene autotemcel), Lyfgenia (lovotibeglogene autotemcel), Omvoh (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 (eladocogene exuparvovec-tneq) and Vyalev (foscarnidopa/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 (eladocogene exuparvovec-tneq) from the drug list.   |
| 02/17/25 | Additions of Otulfi (ustekinumab-aaaz) and Pyzchiva (ustekinumab-ttwe) SC injections and IV infusions to the drug list.  |
| 04/01/25 | Revision: Added Bkernv (eculizumab-aeab) IV infusion and Epysqli (eculizumab-aagh) IV infusion to the drug list. Removed Vyalev (foscarnidopa/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 Bkernv (eculizumab-aeab) IV infusion and Epysqli (eculizumab-aagh) IV infusion from the drug list.   |
| 07/01/25 | Added Bomynta (denosumab-bnht) and Conexence (denosumab-bnht) SC injections, and removed Wezlana (ustekinumab-auub), Otulfi (ustekinumab-aaaz), 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.  |