

09-J4000-30

Original Effective Date: 07/01/22

Reviewed: 08/14/24

Revised: 05/15/25

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.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions
Related Guidelines	Other	References	Updates	

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 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 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 Provider-Administered 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
Wezlana (ustekinumab-auub) SC injection	Q5137 (entered market with an assigned code)	01/01/25
Wezlana (ustekinumab-auub) IV infusion	Q5138 (entered market with an assigned code)	01/01/25
Otulfu (ustekinumab-aaaz) SC injection	J3590 (updated to Q9999 on 04/01/25)	02/15/25
Otulfu (ustekinumab-aaaz) IV infusion	J3590 (updated to Q9999 on 04/01/25)	02/15/25
Pyzchiva (ustekinumab-ttwe) SC injection	Q9996 (entered market with an assigned code)	02/15/25
Pyzchiva (ustekinumab-ttwe) IV infusion	Q9997 (entered market with an assigned code)	02/15/25
Bkemv (eculizumab-aeeb) IV infusion	Q5152 (entered market with an assigned code)	04/01/25
Epysqli (eculizumab-aagh) IV infusion	Q5151 (entered market with an assigned code)	04/01/25
Boruzu (injection, bortezomib (boruzu)) SC injection and IV infusion	J9054 (entered market with an assigned code)	05/01/25
Imuldosa (ustekinumab-srlf) SC injection	J3590	05/01/25
Imuldosa (ustekinumab-srlf) IV infusion	J3590	05/01/25
Tepylute (thiotepa) IV infusion	J9999	05/15/25

BILLING/CODING INFORMATION:

HCPCS Coding

A9699	Radiopharmaceutical, therapeutic, 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.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

REFERENCES:

1. 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>
2. Bkerv (eculizumab-aeeb injection, for intravenous use) [package insert]. Amgen, Inc.; Thousand Oaks, CA. October 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761333s001lbl.pdf
3. Epysqli (eculizumab-aagh injection, for intravenous use) [package insert]. Samsung Bioepis Co., Ltd. Republic of Korea. January 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761340Orig1s002lbl.pdf
4. Imuldosa (ustekinumab-srlf injection, for subcutaneous or intravenous use) [package insert]. Accord BioPharma Inc. Raleigh, NC: October 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761364s000lbl.pdf
5. Otulfi (ustekinumab-aaaz) [package insert]. Fresenius Kabi USA, LLC. Lake Zurich, IL: September 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761379s001lbl.pdf

6. Pyzchiva (ustekinumab-ttwe) [package insert]. Sandoz Inc. Princeton, NJ: December 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761373s002,761425s002lbl.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
8. Wezlana (ustekinumab-auub) [package insert]. Amgen Inc. Thousand Oaks, CA: October 2023.

COMMITTEE AP PROVAL:

This policy was approved by the Florida Blue Pharmacy Policy Committee on 08/14/24.

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 (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), 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.
10/15/25	Addition of Posfrea (palonosetron) injection to the drug list.
10/30/24	Addition of Pavblu (aflibercept-ayyh) injection to the drug list.
11/15/24	Addition of Kebilidi (eladocogene 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 (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 Bkempv (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 (aflibercept-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.