

09-J4000-30

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Reviewed: 06/14/23

Revised: 04/03/24

## Subject: New-To-Market Program for Provider-Administered 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 Provider-Administered Medications affords Florida Blue the ability to review, evaluate, assess coverage status, and develop programs for newly marketed, provider-administered medications on the member's medical benefit prior to coverage. Certain provider-administered 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)
- Administered by a healthcare provider
- 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 Provider-Administered 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 Provider-Administered Medications Drug List will be denied as a non-covered benefit.

Medications identified on the New-To-Market Program for Provider-Administered 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 Provider-Administered Medications Drug List**

Medication Name	Initial Unclassified HCPCS Code	Date Added
Elevidys (delandistrogene moxeparvovec-rokl)	J3590 (specific code J1413 effective 1/1/24)	07/19/23
Winrevair (sotatercept-csrk)	J3590	04/02/24

**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
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. Elevidys (delandistrogene moxeparovvec-rokl) [package insert]. Sarepta Therapeutics, Inc.; Cambridge, MA. June 2023. Available at: <https://www.fda.gov/media/169679/download>.
2. Winrevair (sotatercept-csrk) [package insert]. Merck Sharp & Dohme LLC; Rahway, NJ. March 2024. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/761363s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761363s000lbl.pdf)

## COMMITTEE APPROVAL:

This policy was approved by the Florida Blue Pharmacy Policy Committee on 06/14/23.

## 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 dezaparovvec) 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 dezaparovvec) from the drug list.
07/15/23	Review of guideline with no changes. Additions of Lantidra (donislecel-jujn) and Roctavian (valoctocogene roxaparovvec-rvox) to the drug list.
07/19/23	Addition of Elevidys (delandistrogene moxeparovvec-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 (cipaglusosidase 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 (cipaglusosidase alfa-atga), Rivfloza (nedosiran), and Roctavian (valoctocogene roxaparovvec-rvox) from the drug list.
04/02/24	Addition of Winrevair (sotatercept-csrk) to the drug list.

