

**This document applies to the following:**

| Formulary                                      | Applies                             |
|------------------------------------------------|-------------------------------------|
| Standard Control (SF)                          | <input type="checkbox"/>            |
| Standard Control – Choice (SCCF)               | <input type="checkbox"/>            |
| Preferred Drug Plan Design (PDPD)              | <input type="checkbox"/>            |
| Advanced Control Specialty (ACSF)              | <input type="checkbox"/>            |
| Advanced Control Specialty – Choice (ACSCF)    | <input type="checkbox"/>            |
| Managed Medicaid Template (MMT)                | <input type="checkbox"/>            |
| Marketplace (MF)                               | <input checked="" type="checkbox"/> |
| Aetna Small Group Affordable Care Act (SG ACA) | <input type="checkbox"/>            |
| Aetna Health Exchange (AHE)                    | <input checked="" type="checkbox"/> |
| Aetna Individual Lives (IVL)                   | <input checked="" type="checkbox"/> |
| Value (VF)                                     | <input type="checkbox"/>            |
| New to Market (NTM)                            | <input type="checkbox"/>            |

| Formulary                                                 | Applies                  |
|-----------------------------------------------------------|--------------------------|
| Standard Formulary Chart (SFC)                            | <input type="checkbox"/> |
| Basic Control Chart Preferred Drug Plan Design (BCC PDPD) | <input type="checkbox"/> |
| Advanced Control Specialty Formulary Chart (ACSFC)        | <input type="checkbox"/> |
| Value Formulary Chart (VFC)                               | <input type="checkbox"/> |
| Medical Benefit                                           | <input type="checkbox"/> |
| Medical Benefit: Advanced Biosimilars First               | <input type="checkbox"/> |
| Combined Benefit Medical (CBM)                            | <input type="checkbox"/> |
| Medical Benefit: Managed Medicaid (MMMB)                  | <input type="checkbox"/> |
| Medicare Part B                                           | <input type="checkbox"/> |
| Medicare Part B: Advanced Biosimilars First               | <input type="checkbox"/> |

# Exceptions Criteria

## Colony Stimulating Factors – Short Acting

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Marketplace Formulary (MF), Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE), and Aetna Individual Lives (IVL) Formulary

## Plan Design Summary

This program applies to the short-acting colony stimulating factor products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with Granix, Neupogen, Nypozi, Releuko, or Zarxio and for members who are new to treatment with Leukine for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

## Table. Colony Stimulating Factors – Short Acting

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

|                     |
|---------------------|
| Reference number(s) |
| 6901-D              |

|           | Product(s)                                                                                                                                                                                                                                      |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Preferred | <ul style="list-style-type: none"> <li>Nivestym (filgrastim-aafi)</li> </ul>                                                                                                                                                                    |
| Target    | <ul style="list-style-type: none"> <li>Granix (TBO-filgrastim)</li> <li>Leukine (sargramostim)</li> <li>Neupogen (filgrastim)</li> <li>Nypozi (filgrastim-txid)</li> <li>Releuko (filgrastim-ayow)</li> <li>Zarxio (filgrastim-sndz)</li> </ul> |

## Exception Criteria

Coverage for the targeted products, Neupogen, Nypozi, Granix, Releuko, or Zarxio, is provided when the member has had a documented intolerable adverse event to the preferred product and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

Coverage for the targeted product, Leukine, is provided when one of the following criteria is met:

- Member has had a documented inadequate response or an intolerable adverse effect to the preferred product.
- Leukine is being requested for an indication that is not FDA-approved for the preferred product.
- Member is currently receiving treatment with Leukine, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.

## References

1. Zarxio [package insert]. Princeton, NJ: Sandoz, Inc.; October 2024.
2. Neupogen [package insert]. Thousand Oaks, CA: Amgen, Inc; April 2023.
3. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2023.
4. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; August 2023.
5. Nivestym [package insert]. Lake Forest, IL: Hospira Inc., a Pfizer company: February 2024.
6. Nypozi [package insert]. San Diego, CA: Tanvex BioPharma USA, Inc.; June 2024.
7. Releuko [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; August 2023.