

This policy applies to the following:

|   |                                 |                     |   |                                     |   |             |
|---|---------------------------------|---------------------|---|-------------------------------------|---|-------------|
| Standard Control (SF)                       | Managed Medicaid Template (MMT) | ACSF Chart (ACSCF)  | ✓ | Medical Benefit                     | Medicare Part B                             | Reference # |
| Standard Control – Choice (SCCF)            | Marketplace (MF)                | SF Chart (SFC)      |   | Medical: Advanced Biosimilars First | Medicare Part B: Biosimilars First          | 5626-D      |
| Preferred Drug Plan Design (PDPD)           | Aetna Health Exchange (AHE)     | VF Chart (VFC)      |   | Medical Benefit: Managed Medicaid   | Medicare Part B: Advanced Biosimilars First |             |
| Advanced Control Specialty (ACSF)           | IVL                             | New to Market (NTM) |   | Medical Benefit: Add-on             |   |             |
| Advanced Control Specialty – Choice (ACSCF) | Value (VF)                      |                     |   |                                     |   |             |

## EXCEPTIONS CRITERIA ERYTHROPOIESIS STIMULATING AGENTS

### PREFERRED PRODUCTS: ARANESP AND PROCRIT

#### POLICY

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

#### I. PLAN DESIGN SUMMARY

This program applies to the erythropoiesis stimulating agents specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products 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 a targeted product.

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

Table. Erythropoiesis stimulating agents

|            | Product(s)   |
|------------|--|
| Preferred* | <ul style="list-style-type: none"> <li>• <b>Aranesp</b> (darbepoetin alfa)</li> <li>• <b>Procrit</b> (epoetin alfa)</li> </ul>   |
| Targeted   | <ul style="list-style-type: none"> <li>• <b>Epogen</b> (epoetin alfa)</li> <li>• <b>Mircera</b> (methoxy polyethylene glycol-epoetin beta)</li> <li>• <b>Retacrit</b> (epoetin alfa-epbx)</li> </ul> |

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

#### II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

##### A. Epogen

Coverage for Epogen is provided when both of the following criteria are met:

1. Member has had a documented intolerable adverse event with Procrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
2. Member has a documented inadequate response or intolerable adverse event with Aranesp when prescribed for the treatment of anemia due to chronic kidney disease or the treatment of anemia due to myelosuppressive chemotherapy in cancer.

##### B. Mircera

Coverage for Mircera is provided when the member has a documented inadequate response or intolerable adverse event with both of the preferred products, Aranesp and Procrit.

This policy applies to the following:

|  |   |  |                                 |  |                     |   |                                     |  |   |             |
|--|---|--|---------------------------------|--|---------------------|---|-------------------------------------|--|---|-------------|
|  | Standard Control (SF)                       |  | Managed Medicaid Template (MMT) |  | ACSF Chart (ACSFC)  | ✓ | Medical Benefit                     |  | Medicare Part B                             | Reference # |
|  | Standard Control – Choice (SCCF)            |  | Marketplace (MF)                |  | SF Chart (SFC)      |   | Medical: Advanced Biosimilars First |  | Medicare Part B: Biosimilars First          | 5626-D      |
|  | Preferred Drug Plan Design (PDPD)           |  | Aetna Health Exchange (AHE)     |  | VF Chart (VFC)      |   | Medical Benefit: Managed Medicaid   |  | Medicare Part B: Advanced Biosimilars First |             |
|  | Advanced Control Specialty (ACSF)           |  | IVL                             |  | New to Market (NTM) |   | Medical Benefit: Add-on             |  |   |             |
|  | Advanced Control Specialty – Choice (ACSCF) |  | Value (VF)                      |  |                     |   |                                     |  |   |             |

### C. Retacrit

Coverage for Retacrit is provided when both of the following criteria are met:

1. Member has had a documented intolerable adverse event with Procrit, 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).
2. Member has a documented inadequate response or intolerable adverse event with Aranesp when prescribed for the treatment of anemia due to chronic kidney disease or the treatment of anemia due to myelosuppressive chemotherapy in cancer.

### REFERENCES

1. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2019.
2. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; July 2018.
3. Procrit [package insert]. Horsham, PA: Janssen Products, LP; July 2018.
4. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; March 2023.
5. Retacrit [package insert]. New York, NY: Pfizer Labs; April 2023.