

This policy applies to the following:

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

| Reference # |
|-------------|
| 4309-D |

EXCEPTIONS CRITERIA

FACTOR IX PRODUCTS

PREFERRED PRODUCTS: IDELVION & REBINYN

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 Factor IX products specified in this policy. Coverage for targeted product 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 members who are new to treatment with a targeted product for the first time.

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

Table. Factor IX Products

| | Product(s) |
|------------|---|
| Preferred* | <ul style="list-style-type: none"> Idelvion (coagulation factor IX [recombinant], albumin fusion protein) Rebinyn (coagulation factor IX [recombinant], glycoPEGylated) |
| Targeted | <ul style="list-style-type: none"> Alprolix (coagulation factor IX [recombinant], Fc fusion protein) |

*: 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.

Coverage for a targeted product is provided when any of the following criteria are met:

- Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has experienced a documented inadequate response, intolerable adverse event, or has a contraindication to both of the preferred products.
- Member is requesting the targeted drug for routine prophylaxis to reduce the frequency of bleeding episodes, and the member has experienced a documented inadequate response, intolerable adverse event, or has a contraindication to Idelvion.

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| | | | | | | | | | |
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| | Preferred Drug Plan Design (PDPD) | | Managed Medicaid Template (MMT) | ✓ | SF Chart (SFC) | | Medical Benefit: Biosimilars First | | Medicare Part B: Biosimilars First |
| ✓ | Advanced Control Specialty (ACSF) | | Marketplace (MF) | ✓ | VF Chart (VFC) | | Medical Benefit: Add-on | | Medicare Part B: Add-on |
| ✓ | Balanced (BF) | | New to Market (NTM) | | IVL | | Medical Benefit: Managed Medicaid | | Aetna Health Exchange (AHE) |

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REFERENCES

1. Alprolix [package insert]. Cambridge, MA: Biogen Idec Inc.; October 2020.
2. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; July 2020.
3. Rebinyn [package insert]. DK-2880 Bagsvaerd, Denmark: Novo Nordisk A/S; June 2020.