Reference number(s)
4659-D

This document applies to the following:

Product	Applies
Medicare Part B	☑
Medicare Part B: Advanced Biosimilars First	☑

Medicare Part B Step Therapy Asthma

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

These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary

This program applies to the asthma products specified in this document. Coverage for the non-preferred products are 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 non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Asthma Products

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

	Products
Preferred	• Fasenra (benralizumab) • Tezspire (tezepelumab-ekko) • Xolair (omalizumab)
Non-preferred	• Cinqair (reslizumab) • Nucala (mepolizumab)

Step Therapy Criteria

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

Cinqair

Coverage for Cinqair is provided when either of the following criteria is met:

- Member has received treatment with Cinqair in the past 365 days.
- Member has both of the following:
    - Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Fasenra and Tezspire.
    - Member has either of the following:
        - A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with the preferred product Xolair.
        - A pretreatment serum IgE level of less than 30 IU/mL.

Nucala

Coverage for Nucala is provided when either of the following criteria is met:

- Member has received treatment with Nucala in the past 365 days.
- Member meets any of the following:
    - Member has a comorbidity of nasal polyps and meets either of the following:
        - A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with the preferred product Xolair.
        - A pretreatment serum IgE level of less than 30 IU/mL.
    - Member meets both of the following:
        - Member meets either of the following:
            - Member is 12 years of age and older and has a documented inadequate response or an intolerable adverse event with both of the preferred products, Fasenra and Tezspire.
            - Member is less than 12 years of age and has a documented inadequate response or an intolerable adverse event with the preferred product Fasenra.
        - Member has either of the following:

- A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with the preferred product Xolair.
- A pretreatment serum IgE level of less than 30 IU/mL.

- Member has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and has a documented inadequate response or intolerable adverse event with the preferred product Fasenra.

References

1. Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; June 2020.
2. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2024.
3. Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2023.
4. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2023.
5. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.