This policy applies to the following:

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

Reference #
4659-D

EXCEPTIONS CRITERIA

ASTHMA

PREFERRED PRODUCTS: FASENRA AND XOLAIR

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 asthma products 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 members who are new to treatment with the targeted product for the first time.

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

Table. Asthma products

	Product(s)
Preferred*	• **Fasenra** (benralizumab) • **Xolair** (omalizumab)
Targeted	• **Cinqair** (reslizumab) • **Nucala** (mepolizumab) • **Tezspire** (tezepelumab-ekko)

*: 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. Cinqair

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

1. Member has received treatment with the targeted product in the past 365 days.
2. Member has both of the following:
   a. Member has a documented inadequate response or intolerable adverse event with Fasenra.
   b. Member has either of the following:

This policy applies to the following:

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

Reference #
4659-D

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

B. Nucala

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

1. Member has received treatment with the targeted product in the past 365 days.
2. Member meets any of the following:
   a. Member has a comorbidity of nasal polyps and meets either of the following:
      i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.
   b. Member is less than 12 years of age and meets either of the following:
      i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.
   c. Member is 12 years of age or older and meets both of the following:
      i. Member has a documented inadequate response or an intolerable adverse event with Fasenra.
      ii. Member has either of the following:
         aa. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
         bb. A pretreatment serum IgE level of less than 30 IU/mL.

C. Tezspire

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

1. Member has received treatment with the targeted product in the past 365 days.
2. Member meets both of the following:
   a. The member has either of the following:
      i. Blood eosinophil count of at least 150 cells per microliter and has had a documented inadequate response or an intolerable adverse event with Fasenra.
      ii. Blood eosinophil count of less than 150 cells per microliter.
   b. The member has either of the following:
      i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.

This policy applies to the following:

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

Reference #
4659-D

REFERENCES

1. Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; June 2020.
2. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
3. Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2023.
4. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2023.
5. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; March 2023.

This policy applies to the following:

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

Reference #
4659-D