

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2024 P 1415-2
Program	Prior Authorization/Notification
Medications	Tezspire [™] (tezepelumab-ekko)*
	*This program applies to the prefilled pen for self-administration.
P&T Approval Date	7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

Tezspire (tezepelumab) is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Limitations of use:

Tezspire is not indicated for relief of acute bronchospasm of status asthmaticus.

2. Coverage Criteria^a:

A. Severe Asthma

1. Initial Authorization

a. Tezspire will be approved based on <u>one</u> of the following criteria:

- (1) <u>All</u> of the following:
 - (a) Patient has been established on therapy with Tezspire under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

-AND-

(b) Documentation of positive clinical response to Tezspire therapy

-AND-

(c) Tezspire is being used as add-on maintenance therapy

-AND-

- (d) Patient is not receiving Tezspire in combination with <u>any</u> of the following:
 - i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
 - ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
 - iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

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-OR-

(2) <u>All</u> of the following:

(a) Diagnosis of severe asthma

-AND-

(b) Tezspire is being used as add-on maintenance therapy

-AND-

(c) Patient is not receiving Tezspire in combination with <u>any</u> of the following:

- i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
- iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Authorization will be issued for 12 months.

2. Reauthorization

a. Tezspire will be approved based on <u>all</u> of the following criteria:

(1) Documentation of positive clinical response to Tezspire therapy

-AND-

(2) Tezspire is being used as add-on maintenance therapy

-AND-

(3) Patient is not receiving Tezspire in combination with <u>any</u> of the following:

- (a) Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- (b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
- (c) Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.



3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place.
- Medical Necessity may be in place.
- The single-dose vial and pre-filled syringe for administration by a healthcare professional is typically covered under the medical benefit. Please refer to the United Healthcare Medical Benefit Drug Policy: "Tezspire[™] (tezepelumab-ekko)."

3. References:

1. Tezspire[™] [package insert]. Thousand Oakes, CA: Amgen Inc.; May 2023.

Program	Prior Authorization/Notification - Tezspire (tezepelumab)
Change Control	
7/2023	New program.
7/2024	Annual review. Specified existing prior authorization for under the medical benefit. Updated reference.