

SENTARA COMMUNITY PLAN (MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; fax to 1-844-305-2331. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization can be delayed.

Drug Requested: Tezspire™ (tezepelumab) (J2356) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

- Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage: Adults and adolescents ≥ 12 years: 210 mg/1.9 mL SubQ, single-dose prefilled syringe or single dose vial once every 4 weeks. Tezspire™ 210mg/1.9ml; 1 syringe or vial=210 billable units.

*Sentara Health Plans considers the use of concomitant therapy with Cinqair®, Dupixent®, Fasenra®, Nucala®, and Xolair® to be experimental and investigational. Safety and efficacy of these combinations have **NOT** been established and will **NOT** be permitted. In the event a member has an active Cinqair®, Dupixent®, Fasenra®, Nucala®, and Xolair® authorization on file, all subsequent requests for Tezspire™ will **NOT** be approved.

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- Has the member been approved for Tezspire™ previously through the Sentara pharmacy department?
 Yes No

DIAGNOSIS: Severe Asthma

Initial Authorization: 6 months

1. Is the member 12 years of age or older? Yes No
2. Does the member have a diagnosis of severe asthma*? Yes No
3. Will coadministration with another monoclonal antibody be avoided (i.e. omalizumab, mepolizumab, reslizumab, benralizumab, and dupilumab)? Yes No
4. Will Tezspire™ be used for add-on maintenance treatment in members regularly receiving both (unless otherwise contraindicated) of the following:
 - Medium to high dose inhaled corticosteroids **AND**
 - An additional controller medication (i.e. long-acting beta agonist, leukotriene modifiers?)
 Yes No
5. Has the member had two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) or one exacerbation resulting in hospitalization? Yes No
6. Does the member have at least one of the following for assessment of clinical status:
 - Use of systemic corticosteroids
 - Use of inhaled corticosteroids
 - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
 - Forced expiratory volume in 1 second (FEV1)?
 Yes No
7. Has the member tried and failed an adequate trial of the 2 different preferred products (Fasenra® and Xolair®)? Yes No N/A

If N/A selected for question 7, please answer the following:

1. Does the member lack an eosinophilic phenotype with blood eosinophils ≥ 150 cells/ μ L? **OR**
 Yes No
2. Does the member have a serum IgE level < 30 IU/mL? **OR** Yes No
3. Does the member have another predicted intolerance to the preferred agents?
 Yes No

Please provide explanation: _____

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DIAGNOSIS: Severe Asthma

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

1. Has the member been assessed for toxicity? Yes No
2. Does the member have improvement in asthma symptoms or asthma exacerbations as evidenced by a decrease in one or more of the following:
 - Use of systemic corticosteroids
 - Hospitalizations
 - ER visits
 - Unscheduled visits to healthcare provider
 - Improvement from baseline in forced expiratory volume in 1 second (FEV1)? Yes No

Components of severity for classifying asthma as severe may include any of the following (not all inclusive):

- Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma that requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times per week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) < 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

DIAGNOSIS: Chronic rhinosinusitis with nasal polyps (CRSwNP)

Initial Authorization: 6 months

1. Is the member 12 years of age or older? Yes No
2. Does the member have a diagnosis of bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks? Yes No
3. Will coadministration with another monoclonal antibody be avoided (e.g. omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab)? Yes No
4. Has the member tried and failed an 8-week trial of intranasal corticosteroid therapy? Yes No

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5. Will Tezspire be used in combination with intranasal corticosteroids (unless intolerant or contraindicated)? Yes No
6. Has the member tried and failed an adequate trial of the preferred product, Xolair (unless contraindicated or clinically inappropriate)? Yes No

DIAGNOSIS: Chronic rhinosinusitis with nasal polyps (CRSwNP)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

1. Has the member been assessed for toxicity? Yes No
2. Has the member experienced a disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool (e.g., nasal polyposis score [NPS], nasal congestion [NC] symptom severity score, sinonasal outcome test-22 [SNOT-22]). **OR** Yes No
3. Did the member have improvement in at least one of the following response criteria:
- Reduction in nasal polyp size
 - Reduction in need for systemic corticosteroids
 - Improvement in quality of life
 - Improvement in sense of smell
 - Reduction of impact of comorbidities?

Medication being provided by: Please check applicable box below.

- Location/site of drug administration:** _____
NPI or DEA # of administering location: _____

OR

- Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****