

GCHP Medi-Cal Clinical Guidelines Tezepelumab (Tezspire™)

| PA Criteria | Criteria Details |
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| Covered Uses (FDA Approved Indication) | Add-on maintenance treatment of severe asthma. |
| Exclusion Criteria | <ul style="list-style-type: none"> • Monotherapy use (tezepelumab is add on therapy to the current asthma treatment regimen). • Tezepelumab will not be used concurrently with other monoclonal antibodies with similar indications such as dupilumab, mepolizumab, omalizumab, reslizumab or benralizumab. |
| Required Medical Information | <p>Dosage form that is being requested for administration during the medical visit (Prefilled Autoinjector pen vs. Prefilled Syringe)</p> <ul style="list-style-type: none"> • Tezspire™ Autoinjectors pen: FDA approved for self or caregiver administration with proper training. • Tezspire™ Prefilled syringe: FDA approved for administration by health care provider. <ul style="list-style-type: none"> • Documented diagnosis of asthma for at least 12 months. • Patient is adherent on medium or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller (such as long acting beta2 agonist (LABA), with or without oral corticosteroids (OCS). • Patient has persistent uncontrolled asthma as defined by at least one of the following: <ul style="list-style-type: none"> ○ An Asthma Control Questionnaire (ACQ6) score of 1.5 or more, or an Asthma Control Test (ACT) score less than 20 at baseline. ○ A history of at least two asthma exacerbation events within prior 12 months. ○ A history of at least one severe asthma exacerbation resulting in hospitalization within prior 12 months. ○ Patient has inadequate asthma control (for example, hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimal dosages: <ol style="list-style-type: none"> i. Inhaled corticosteroid; and ii. Long acting beta2-agonist, leukotriene modifier, or sustained release theophylline). |
| Age Restriction | 12 years of age and older |
| Prescriber Restrictions | Must be prescribed by or in consultation with a pulmonologist, allergist or immunologist. |

| Coverage Duration | Prefilled syringes: One dose to allow administration of starting dose with the goal of transitioning to the autoinjector or prefilled syringe for maintenance treatment at home (provided by the pharmacy). | | | | | | |
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| Other Criteria | <p>Criteria adapted from DHCS March 2024</p> <p>Tezepelumab (Tezspire™) is available for self-administration in the form of an autoinjector pen, which are administered by the member or a caregiver at home. Tezspire™ autoinjector pen should be provided to the member by a pharmacy through pharmacy benefit.</p> <p>Prefilled syringes: Requests will be approved for one-time, if the health care provider prefers to administer the first dose for new start requests, by obtaining it though the practice.</p> <p>If administration by the provider is requested beyond the time frames shown above, the provider must include reason(s) on the renewal referral stating why the member or caregiver cannot obtain the drug through the pharmacy benefit for self or caregiver administration.</p> <table><tr><th>HCP</th><th>Description</th><th>Dosing, Units</th></tr><tr><td>J2356</td><td>Injection, tezepelumab-ekko, 1 mg (Tezspire™ autoinjector pen & Tezspire™ prefilled syringe)</td><td><ul style="list-style-type: none">• Recommended (& maximum) dose: 210 mg.• Administered as 210 mg. subcutaneously once every four weeks.<p>1 HCP unit = 1 mg, therefore a 210 mg dose is billed as a count of 210 units of service.</p></td></tr></table> | HCP | Description | Dosing, Units | J2356 | Injection, tezepelumab-ekko, 1 mg (Tezspire™ autoinjector pen & Tezspire™ prefilled syringe) | <ul style="list-style-type: none">• Recommended (& maximum) dose: 210 mg.• Administered as 210 mg. subcutaneously once every four weeks. <p>1 HCP unit = 1 mg, therefore a 210 mg dose is billed as a count of 210 units of service.</p> |
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| STATUS | DATE REVISED | REVIEW DATE | APPROVED / REVIEWED BY | EFFECTIVE DATE |
|----------|--------------|-------------|--|----------------|
| Created | 5/1/2024 | 5/1/2024 | Lily Yip, Director of Pharmacy Services; Yoonhee Kim, Clinical Programs Pharmacist | N/A |
| Approved | N/A | 5/15/2024 | Pharmacy & Therapeutics (P&T) Committee | 3/1/2025 |
| Approved | N/A | 7/18/2024 | Medical Advisory Committee (MAC) | 3/1/2025 |
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