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| ISSUE DATE December 9, 2022 | EFFECTIVE DATE January 9, 2023 | NUMBER *See below |
| SUBJECT Prior Authorization of Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP (Formerly Monoclonal Antibodies – Anti-IL, Anti-IgE) – Pharmacy Services | BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs | |

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISE to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISE-Enrollment.aspx>.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP to the appropriate managed care organization.

BACKGROUND:

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| *01-22-50 | 09-22-49 | 27-22-37 | 33-22-47 |
| 02-22-34 | 11-22-34 | 30-22-40 | |
| 03-22-33 | 14-22-34 | 31-22-53 | |
| 08-22-58 | 24-22-42 | 32-22-34 | |

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included in the Preferred Drug List (PDL).
- Changes in the status of drugs and products on the PDL from preferred to non-preferred and non-preferred to preferred.
- New quantity limits.
- Therapeutic classes of drugs and products to be added to or deleted from the PDL.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 14, 2022, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP:

- Revision of the Statewide PDL class name from Monoclonal Antibodies – Anti-IL, Anti-IgE (MABs – Anti-IL, Anti-IgE) to Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP (MABs – Anti-IL, Anti-IgE, Anti-TSLP).
- Revision of the guidelines for a diagnosis of chronic idiopathic urticaria.
- Revision of the guideline for a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) related to prednisolone.
- Addition of a guideline for a beneficiary with severe EGPA that the beneficiary has a history of therapeutic failure of or a contraindication or an intolerance to rituximab or cyclophosphamide.
- Revision of the guideline for a diagnosis of hypereosinophilic syndrome related to systemic glucocorticoids.
- Addition of a guideline that for all other diagnoses, the beneficiary has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines.
- Revision of the renewal guideline for a diagnosis of EGPA.

The revisions to the guidelines to determine medical necessity of prescriptions for Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP submitted for prior authorization, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages

in the SECTION II chapter related to Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I

Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II

Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP (MABs – Anti-IL, Anti-IgE, Anti-TSLP)

A. Prescriptions That Require Prior Authorization

All prescriptions for MABs – Anti-IL, Anti-IgE, Anti-TSLP must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Dupixent (dupilumab), see the prior authorization guidelines related to Dupixent (dupilumab); **OR**
2. Is prescribed the MAB – Anti-IL, Anti-IgE, Anti-TSLP for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Is prescribed the MAB – Anti-IL, Anti-IgE, Anti-TSLP by or in consultation with an appropriate specialist (i.e., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); **AND**
6. If currently using a different MAB – Anti-IL, Anti-IgE, Anti-TSLP than requested, will discontinue the other MAB – Anti-IL, Anti-IgE, Anti-TSLP prior to starting the requested agent; **AND**
7. For a non-preferred MAB – Anti-IL, Anti-IgE, Anti-TSLP, **one** of the following:
 - a. Has a history of therapeutic failure of or an intolerance or a contraindication of the preferred MABs – Anti-IL, Anti-IgE, Anti-TSLP approved or medically accepted for the beneficiary's indication
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred MAB – Anti-IL, Anti-IgE, Anti-TSLP

See the Preferred Drug List for the list of preferred MABs – Anti-IL, Anti-IgE, Anti-TSLP at: <https://papdl.com/preferred-drug-list>;

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AND

8. For a diagnosis of asthma, **both** of the following:
- a. Has an asthma severity that is consistent with the FDA-approved indication for the prescribed MAB – Anti-IL, Anti-IgE, Anti-TSLP despite maximal therapeutic doses of or intolerance or contraindication to standard asthma controller medications based on current national treatment guidelines for the diagnosis and management of asthma
 - b. Will use the requested MAB – Anti-IL, Anti-IgE, Anti-TSLP in addition to standard asthma controller medications as recommended by current national treatment guidelines for the diagnosis and management of asthma;

AND

9. For a diagnosis of chronic idiopathic urticaria, **both** of the following:
- a. Has a history of urticaria for a period of at least 6 weeks
 - b. **One** of the following:
 - i. Requires systemic steroids to control urticarial symptoms
 - ii. Has a history of therapeutic failure of or a contraindication or an intolerance to maximum tolerated doses of an H1 antihistamine taken for at least 2 weeks;

AND

10. For a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), **all** of the following:
- a. Has a diagnosis of EGPA supported by **all** of the following:
 - i. A history of asthma,
 - ii. A history of absolute blood eosinophil count ≥ 1000 cells/microL or blood eosinophil level $> 10\%$ of leukocytes,
 - iii. A history of at least **one** of the following:
 - a) Histopathological evidence of **one** of the following:
 - (i) Eosinophilic vasculitis,
 - (ii) Perivascular eosinophilic infiltration,
 - (iii) Eosinophil-rich granulomatous inflammation,
 - b) Neuropathy, mono or poly (motor deficit or nerve conduction abnormality),

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- c) Pulmonary infiltrates, non-fixed,
 - d) Sino-nasal abnormality,
 - e) Cardiomyopathy,
 - f) Glomerulonephritis,
 - g) Alveolar hemorrhage,
 - h) Palpable purpura,
 - i) Positive test for ANCA,
- b. **One** of the following:
- i. Requires systemic glucocorticoids to maintain remission
 - ii. Has a contraindication or an intolerance to systemic glucocorticoids,
- c. For a beneficiary with severe EGPA as defined by national treatment guidelines, has a history of therapeutic failure of or a contraindication or an intolerance to rituximab or cyclophosphamide;

AND

11. For a diagnosis of hypereosinophilic syndrome (HES), **all** of the following:
- a. Has documented FIP1L1-PDGFR α -negative HES with organ damage or dysfunction,
 - b. Has a blood eosinophil count ≥ 1000 cells/microL,
 - c. **One** of the following:
 - i. Requires or has required systemic glucocorticoids to maintain remission
 - ii. Has a contraindication or an intolerance to systemic glucocorticoids;

AND

12. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines; **AND**
13. For Xolair (omalizumab) for a diagnosis of asthma, has a diagnosis of allergen-induced asthma (allergic asthma confirmed by either a positive skin test or radioallergosorbent test) to an unavoidable perennial aeroallergen (e.g., pollen, mold, dust mite, etc.); **AND**
14. For Cinqair (reslizumab) for a diagnosis of asthma with an eosinophilic phenotype, has an absolute blood eosinophil count ≥ 400 cells/microL; **AND**
15. For Nucala (mepolizumab) for a diagnosis of asthma, has asthma with an eosinophilic phenotype with absolute blood eosinophil count ≥ 150 cells/microL; **AND**

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16. For Fasenra (benralizumab), has asthma with an eosinophilic phenotype with absolute blood eosinophil count ≥ 150 cells/microL; **AND**
17. If a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR MABs – ANTI-IL, ANTI-IgE, ANTI-TSLP: The determination of medical necessity of a request for renewal of a prior authorization for a MAB – Anti-IL, Anti-IgE, Anti-TSLP that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Is prescribed a MAB – Anti-IL, Anti-IgE, Anti-TSLP by or in consultation with an appropriate specialist (i.e., pulmonologist, allergist, immunologist, dermatologist, rheumatologist, etc.); **AND**
3. Is not using the requested MAB – Anti-IL, Anti-IgE, Anti-TSLP in combination with another MAB – Anti-IL, Anti-IgE, Anti-TSLP; **AND**
4. For a diagnosis of asthma, **both** of the following:
 - a. Has measurable evidence of improvement in the severity of the asthma condition
 - b. Continues to use the requested MAB – Anti-IL, Anti-IgE, Anti-TSLP in addition to standard asthma controller medications as recommended by current national treatment guidelines for the diagnosis and management of asthma;

AND

5. For a diagnosis of chronic idiopathic urticaria, **both** of the following:
 - a. Experienced improvement of symptoms
 - b. Has a documented rationale for continued use;

AND

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6. For a diagnosis of HES or EGPA, has **one** of the following:
 - a. Measurable evidence of improvement in disease activity
 - b. Reduction in use of systemic glucocorticoids for this indication;

AND

7. If a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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