American Lung Association®

Severe Asthma and Biologics Decision Support Tool for Primary Care Providers

This tool serves as a guide for primary care providers to assess if a biologic may be beneficial for patients with severe asthma. Health plans may prefer one biologic over another and may require a prior authorization. Review patient's insurance criteria for necessary documentation submission.

If patient has confirmed uncontrolled severe persistent asthma, he/she/they may be eligible for a biologic. The patient should be referred to an allergist/pulmonologist for additional tests, such as a blood draw or allergen test (skin or in-vitro). **Biologics may require consultation or be prescribed from an allergist, immunologist, or pulmonologist.**

Baseline checklist for biologic use

- ✓ Confirm severe persistent asthma with at least one of the following[1,§]:
  - ☐ Documentation of hospitalizations due to asthma exacerbations
  - ☐ Use of SABA several times per day, daily[†]
  - ☐ Asthma symptoms throughout the day
  - ☐ Nightly awakenings due to asthma symptoms
  - ☐ FEV1 <60% of predicted
  - ☐ FEV1/FVC reduced >5%
  - ☐ Interference with normal activity is extremely limited
- ✓ Review of proper inhaler technique
- ✓ Address co-morbidities that may trigger asthma, such as allergic rhinitis
- ✓ Review of medications for adequacy and adherence
  - ☐ Patient is being treated with high dose of ICS + LABA, +/- oral corticosteroid, OR
  - ☐ ICS + LTRA, or ICS + theophylline if intolerant to LABA +/- oral corticosteroid
- ✓ Assess smoking status (non-smoker, former smoker, current smoker, smoking cessation)[‡]
- ✓ Refer patient to allergist/immunologist for severe asthma consultation

Phenotype	Biomarker	Testing Method	Blood Count, if applicable	Available Treatments	Treatment Delivery	Patient Age	Mechanism of Action
Allergic (early onset)	IgE*	Blood Skin	IgE >30 IU/mL	Omalizumab (Xolair)	Subcutaneous injection every 2 to 4 weeks	6 years and older	Anti-IgE
Eosinophilic (late onset) – allergic and non-allergic	Eosinophil	Blood Exhaled nitroic oxide (FeNO) Sputum	>150 cells/μl	Mepolizumab (Nucala) – 12 years and older	Subcutaneous injection every 4 weeks	12 years and older	IL-5 inhibitor
		Blood Exhaled nitroic oxide (FeNO) Sputum	>400 cells/μl	Reslizumab (Cinquair) – 18 years and older	Weight-based intravenous therapy every 4 weeks	18 years and older	IL-5 inhibitor
		Blood Exhaled nitroic oxide (FeNO) Sputum	>150 cells/μl	Benralizumab (Fasenra) – 12 years and older	Subcutaneous injection every 4 weeks for 3 doses, then every 8 weeks	12 years and older	IL-5 inhibitor
		Blood Exhaled nitroic oxide (FeNO) Sputum	>150 cells/μl or patient has oral corticosteroid-dependent asthma	Dupilumab (Dupixent) – 6 months and older	Depending on age, subcutaneous injection every other week, or every 4 weeks	6 years and older	IL-4, IL-13 antagonist
Any phenotype (allergic, non-allergic, eosinophilic, or non-eosinophilic)	None required	None required Blood Exhaled nitroic oxide (FeNO) Sputum	None required Documented failure or intolerance to other biologics for eosinophil phenotype or allergic asthma	Tezepelumab (Tezspire) – 12 years and older	Subcutaneous injection every 4 weeks	12 years and older	TSLP antagonist
Neutrophilic	Neutrophil	Sputum		Antibiotics Lifestyle modifications	N/A		N/A

References

1. U.S. Department of Health, National Institutes of Health, National Heart, Lung, and Blood Institute. Expert Panel Report (EPR-3): Guidelines for the Diagnosis and Management of Asthma – Full Report 2007. https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma. Published August, 2007. Accessed February 15, 2023.
2. Xolair. Prescribing information. Genentech; 2021. Accessed February 22, 2023. https://www.gene.com/download/pdf/xolair_prescribing.pdf
3. Cinqair. Prescribing information. Teva; 2020. Accessed February 22, 2023. https://www.cinqair.com/globalassets/cinqair-redesign/prescribinginformation.pdf
4. Dupixent. Prescribing information. Genentech; 2021. Accessed February 22, 2023. https://www.regeneron.com/downloads/dupixent_fpi.pdf
5. Fasenra. Prescribing information. Genentech; 2021. Accessed February 22, 2023. http://www.azpicentral.com/pi.html?product=fasenra
6. Nucala. Prescribing information. Genentech; 2021. Accessed February 22, 2023.
7. Zoumot Z, Busaidi NA, Tashkandi W et al. Tezepelumab for patients with severe uncontrolled asthma: a systematic review and meta-analysis. J Asthma Allergy. 2022;15:1665-1679. Published 2022 Nov 18. doi:10.2147/JAA.S378062
8. Tezspire. Prescribing information. AstraZeneca; 2023. Accessed February 22, 2023. http://www.azpicentral.com/pi.html?product=tezspire
9. *For patients who fall out of the dosing range, omalizumab is not recommended. Please check the prescribing information.

Thank you to sponsors whose funding helped make the development of this resource possible.

March 2024