Asthma and COPD Biologics for Subcutaneous Administration

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Benralizumab

Biologic	Benralizumab (Fasenra®)
Overview	
Mechanism	IL-5 antagonist
Testing Required Before Start	Helminth infections
Serious Side Effects	Hypersensitivity reactions including anaphylaxis
Common Side Effects	Headache and sore throat
Monitoring Parameters	Anaphylaxis/hypersensitivity reactions (during and after administration); peak flow, PFTs, signs of infection
Available Product Formulations	Available in syringe or autoinjector/pen, refrigeration required.
Administration Instructions	Allow to warm to room temperature for ~30 minutes prior to administration. Syringe is for HCP administration. Patient or caregiver may use pen for administration after initial administration with syringe by HCP.
Adult Patients	
Adult Pulmonary Indications & Dosing	Severe eosinophilic asthma: 30mg SQ every 4 weeks for first 3 doses, then once every 8 weeks
Additional Adult Indications & Dosing	Eosinophilic granulomatosis with polyangiitis (EGPA): 30mg SQ every 4 weeks
Adult Dose Considerations	N/A
Pediatric Patients	
Pediatric Pulmonary Indications & Dosing	Severe eosinophilic asthma: Children 6 to <12 years: <35kg: 10mg SQ every 4 weeks for first 3 doses, then once every 8 weeks Children 6 to <12 years: >35kg: 30mg SQ every 4 weeks for first 3 doses, then once every 8 weeks Children > or = 12 years and Adolescents: 30mg SQ every 4 weeks for first 3 doses, then once every 8 weeks
Additional Pediatric Indications & Dosing	None
Pediatric Dose Considerations	N/A

References:

1. Benralizumab. In: Lexi-Drugs. UpToDate Inc; 2025. Updated April 21, 2026. Accessed May 5, 2026. https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/6567401?cesid=2KqgU6d7y

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Reference last updated on 5/5/26 by:

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Depemokimab

Biologic	depemokimab (Exdensur®)
Overview	
Mechanism	• IL-5 antagonist
Testing Required Before Start	• Confirm phenotype with blood eosinophils • Alternative biomarkers include sputum eosinophils and fraction exhaled nitric oxide)
Serious Side Effects	• Hypersensitivity reactions with anaphylaxis
Common Side Effects	• Antibody development, upper respiratory tract infection, allergic rhinitis, influenza, pharyngitis, arthralgia, injection site reaction
Monitoring Parameters	• Signs of infection • Signs of hypersensitivity
Available Product Formulations	Prefilled syringe: 100 mg/mL
Administration Information	• To be administered by a health care provider • Administer via SUBQ injection into the upper arm, thigh, or abdomen (avoid ~2 inches surrounding the navel) • Avoid skin that is tender, bruised, red, or hard. • Administer within 5 minutes of removing cap from needle • Do not lift or remove injector until a second click is heard
Adult Patients	
Adult Pulmonary Indications & Dosing	• Severe eosinophilic asthma: • 100 mg SUBQ once every 6 months
Additional Adult Indications & Dosing	None

Adult Dose Adjustment Considerations	• Renal:
	  • No dose adjustments recommended in the manufacturer's labeling (not studied)
	  • Renal dose adjustment unlikely to be necessary
	• Hepatic:
	  • No dose adjustments recommended in the manufacturer's labeling (not studied)
	  • Hepatic dose adjustment unlikely to be necessary

Pediatric Patients	

Pediatric Pulmonary Indications & Dosing	Severe eosinophilic asthma: • ≥12 years: 100 mg SUBQ once every 6 months
Additional Pediatric Indications & Dosing	None
Pediatric Dose Adjustment Considerations	Renal: • No dose adjustments recommended in the manufacturer's labeling (not studied) • Renal dose adjustment unlikely to be necessary Hepatic: • No dose adjustments recommended in the manufacturer's labeling (not studied) • Hepatic dose adjustment unlikely to be necessary

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1. Lexicomp Online. Depemokimab-ulaa. In: Lexi-Drugs Online. Hudson, OH: UpToDate, Inc. Accessed May 5, 2026. https://online.lexi.com
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Dupilumab

Biologic	Dupilumab (Dupixent®)
Overview	
Mechanism	• Human monoclonal IgG4 antibody, which binds to IL-4 alpha inhibiting IL-4 and IL-13 signaling
Testing Required Before Start	• Blood eosinophil count • Asthma and/or COPD severity • Helminth infection • Vaccine status – avoid live vaccines during therapy
Serious Side Effects	• Dermatologic and hypersensitivity reactions • Ocular surface disorders
Common Side Effects	• Eosinophilia, antibody development, viral infections, injection-site reactions, upper respiratory infections, conjunctivitis, arthralgias
Monitoring Parameters	• Asthma & COPD: ○ Exacerbations, FeNO, symptom control, lung function • General: ○ Signs/symptoms of arthralgia and psoriatic arthritis, hypersensitivity reactions, ocular adverse effects, signs of infection, signs/symptoms of vasculitis or hypereosinophilia, signs/symptoms of psoriasis
Available Product Formulations	• Solution auto-injector (SUBQ) ○ Dupixent 300 mg/2 mL ○ Dupixent 200 mg/1.14 mL • Solution pre-filled syringe (SUBQ) ○ Dupixent 300 mg/2 mL ○ Dupixent 200 mg/1.14 mL ○ Dupixent 100mg/0.67 mL
Administration Information	• General ○ Allow solution to reach room temperature prior to use. Do not remove needle cap while allowing product to reach room temperature. ▪ For 300 mg prefilled syringe and prefilled pen, allow for 45 minutes at room temperature prior to use ▪ For 200 mg prefilled syringe or prefilled pen and for 100 mg prefilled syringe, allow for 30 minutes at room temperature prior to use ○ After removal from the refrigerator, product must be used within 14 days or discarded. Do not heat prefilled pen in microwave, hot water, or direct sunlight. ○ Do not shake. Do not use if solution is discolored or contains particulate matter. Do not administer if window on prefilled pen is yellow (indicates has been used). ○ Patients may self-administer injections after proper training. ▪ Administer as a SUBQ injection into thigh or lower abdomen (avoid ~2 inches surrounding the navel) ▪ Caregiver may administer in upper arm ○ Rotate injection sites, including initial doses. Do not administer into skin that is tender, damaged, bruised, or scarred. ○ For larger initial doses: ▪ Administer the 600 mg initial dose as two 300 mg injections at different sites

	▪ Administer the 400 mg initial dose as two 200 mg injections at different sites ○ Prefilled syringes and pens do not contain a preservative; discard unused portion. • Pediatric ○ Patients ≥12 years of age may self-administer injection under adult supervision after proper training. ○ Doses in patients <12 years of age should be administered by a properly trained caregiver. • Prefilled pen (for use in ages ≥2 years): ○ Remove cap to expose needle. ▪ For patients <12 years, pinch skin and hold pen at a 90-degree angle to the skin. ▪ For patients ≥12 years, no skin pinching is needed. ○ Press and hold the pen firmly against skin until you cannot see needle cover; there will be a click when injection begins and the viewing window will begin to turn yellow; the viewing window will turn completely yellow and there will be a second click; continue pressing pen against skin for a count of 5 to ensure delivery of entire dose. ○ Do not rub skin after injection. Discard pen. • Prefilled syringe (for use in age ≥6 months): ○ Remove needle cap. ○ Pinch skin and hold syringe at a 45-degree angle against skin, relax the pinch, and slowly and steadily inject contents; stop pressing plunger to release needle shield and remove from injection site. ○ Do not rub skin after injection. Discard syringe.
Adult Patients	
Adult Pulmonary Indications & Dosing	• Moderate to severe asthma – eosinophilic phenotype or oral glucocorticoid dependent ○ 400 mg SUBQ x 1, followed by 200 mg SUBQ every other week ▪ - OR - ○ 600 mg SUBQ x 1, followed by 300 mg SUBQ every other week ▪ Preferred dosing for patients with glucocorticoid-dependent asthma or asthma with comorbid atopic dermatitis, allergic fungal rhinosinusitis, or chronic rhinosinusitis with nasal polyps • COPD, eosinophilic phenotype ○ 300 mg SUBQ every other week
Additional Adult Indications & Dosing	• Moderate to severe atopic dermatitis ○ 600 mg SUBQ x 1, followed by 300 mg SUBQ every other week • Bullous pemphigoid: ○ 600 mg SUBQ x 1, followed by 300 mg SUBQ every other week • Eosinophilic esophagitis ○ 300 mg SUBQ once weekly • Prurigo nodularis ○ 600 mg SUBQ x 1, followed by 300 mg SUBQ every other week • Allergic fungal rhinosinusitis ○ 300 mg SUBQ every other week • Chronic rhinosinusitis with nasal polyps

	○ 300 mg SUBQ every other week • Chronic spontaneous urticaria ○ 600 mg SUBQ x 1, followed by 300 mg SUBQ every other week
Adult Dose Adjustments	• Renal ○ No dose adjustments provided in the manufacturer's labeling ○ Need for dose adjustment unlikely • Hepatic ○ No dose adjustments provided in the manufacturer's labeling (not studied)
Pediatric Patients	
Pediatric Pulmonary Indications & Dosing	• Moderate to severe asthma ○ Children 6 to <12 years ▪ 15 to <30 kg: 300 mg SUBQ every 4 weeks ▪ ≥30 kg: 200 mg SUBQ every other week. • Moderate to severe asthma with comorbid moderate to severe atopic dermatitis ○ Children 6 to <12 years ▪ 15 to <30 kg: 600 mg SUBQ x 1 (administered as two 300 mg injections), followed by a maintenance dose of 300 mg SUBQ every 4 weeks ▪ 30 to <60 kg: 400 mg SUBQ x 1 (administered as two 200 mg injections), followed by a maintenance dose of 200 mg SUBQ every other week ▪ ≥60 kg: 600 mg SUBQ x 1 (administered as two 300 mg injections), followed by a maintenance dose of 300 mg SUBQ every other week ○ Children ≥12 years and Adolescents ▪ 400 mg SUBQ x 1 (administered as two 200 mg injections), followed by a maintenance dose of 200 mg SUBQ every other week ▪ - OR - ▪ 600 mg SUBQ x 1 (administered as two 300 mg injections), followed by a maintenance dose of 300 mg SUBQ every other week • Corticosteroid-dependent asthma OR moderate to severe asthma with comorbid moderate to severe atopic dermatitis, chronic sinusitis with nasal polyps or allergic fungal rhinosinusitis ○ 600 mg SUBQ x 1 (administered as two 300 mg injections), followed by a maintenance dose of 300 mg SUBQ every other week
Additional Pediatric Indications & Dosing	• Atopic dermatitis, moderate to severe ○ Infants ≥ 6 months and Children < 6 years (initial loading dose not necessary in patients <6 years) ▪ 5 to <15 kg: 200 mg SUBQ every 4 weeks ▪ 15 to <30 kg: 300 mg SUBQ every 4 weeks ○ Children ≥6 years and Adolescents ▪ 15 to <30 kg: 600 mg SUBQ x 1 (administered as two 300 mg injections), followed by a maintenance dose of 300 mg SUBQ every 4 weeks. ▪ 30 to <60 kg: 400 mg SUBQ x 1 (administered as two 200 mg injections), followed by a maintenance dose of 200 mg SUBQ every other week ▪ ≥60 kg: 600 mg SUBQ x 1 (administered as two 300 mg injections), followed by a maintenance dose of 300 mg SUBQ every other week • Eosinophilic esophagitis ○ Children and Adolescents: ▪ 15 to <30 kg: 200 mg SUBQ every other week

	▪ 30 to <40 kg: 300 mg SUBQ every other week ▪ ≥40 kg: 300 mg SUBQ every week • Rhinosinusitis, allergic fungal ○ Children ≥6 years and Adolescents <18 years ▪ 15 to <30 kg: 300 mg SUBQ every 4 weeks ▪ 30 to <60 kg: 200 mg SUBQ every other week ▪ ≥60 kg: 300 mg SUBQ every other week • Chronic **rhinosinusitis with nasal polyps:** ○ Children ≥12 years and Adolescents: ▪ 300 mg SUBQ every other week. • Urticaria, chronic spontaneous ○ Children ≥12 years and Adolescents <18 years ▪ 30 to <60 kg: 400 mg SUBQ x 1 (administered as two 200 mg injections), followed by a maintenance dose of 200 mg SUBQ every other week ▪ ≥60 kg: 600 mg SUBQ x 1 (administered as two 300 mg injections), followed by a maintenance dose of 300 mg SUBQ every other week
Pediatric Dose Adjustment Considerations	• Renal ○ No dose adjustments provided in the manufacturer's labeling ○ Need for dose adjustment unlikely • Hepatic ○ No dose adjustments provided in the manufacturer's labeling (not studied)

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2. Dupixent (Dupilumab). Prescribing information. Regeneron Pharmaceuticals, Inc. Accessed April 25, 2026. https://www.regeneron.com/downloads/dupixent_fpi.pdf

Reference last updated on 4/25/2026 by:

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Mepolizumab

Biologic	Mepolizumab (Nucala®)
Overview	
Mechanism	• IL-5 antagonist
Testing Required Before Start	• Blood eosinophil count • Asthma and/or COPD severity • Helminth infection • Vaccine status - caution with live vaccines during therapy
Serious Side Effects	• Hypersensitivity reactions with anaphylaxis
Common Side Effects	• Injection-site reactions, headaches, back pain, arthralgias, upper respiratory infections, fatigue, herpes zoster

Monitoring Parameters	• Asthma & COPD:
	  ○ Exacerbations, lung function, symptom control
	• General:
	  ○ Hypersensitivity, herpes zoster symptoms

Available Product Formulations	• Solution auto-injector (SUBQ):
	  ○ Nucala 100 mg/mL
	• Solution pre-filled syringe (SUBQ)
	  ○ Nucala 40 mg/0.4 mL
	  ○ Nucala 100 mg/mL
	• Vial for reconstituted solution (SUBQ)
	  ○ Nucala 100 mg

Administration Information	• General:
	  ○ Administer via SUBQ injection into the upper arm, thigh, or abdomen (avoid ~2 inches surrounding the navel)
	  ○ Avoid skin that is tender, bruised, red, or hard.
	  ○ For the 300 mg dose, administer as 3 separate 100 mg injections into the upper arm, thigh, or abdomen ~2 inches apart if >1 injection administered at same site.
	• Administration of auto-injector or pre-filled syringe:
	  ○ Store in the refrigerator. Allow device to reach room temperature for 30 minutes prior to administration.
	  ▪ Good for 7 days outside refrigerator in carton. Only good for 8 hours outside of the refrigerator if pen or syringe are removed from carton.
	  ○ Initial use is recommended under supervision of health care provider.
	  ○ Self-injection may occur after proper training.
	• Vial for reconstituted solution (SUBQ)
	  ○ Vial is intended for administration by health care provider.
	  ○ Use a polypropylene syringe fitted with a 21- to 27-gauge 0.5-inch (13 mm) needle.
	  ○ Do not shake the reconstituted solution as this could lead to product foaming or precipitation.

	○ If reconstituted solution is not used immediately, store below 30 degrees F, do not freeze, and discard if not used within 8 hours of reconstitution
Adult Patients	
Adult Pulmonary Indications & Dosing	• Severe eosinophilic asthma: 1. 100 mg SUBQ once every 4 weeks • COPD, eosinophilic phenotype: 1. 100 mg SUBQ once every 4 weeks
Additional Adult Indications & Dosing	• Chronic rhinosinusitis with nasal polyps ○ 100 mg SUBQ once every 4 weeks • Eosinophilic granulomatosis with polyangiitis ○ 300 mg SUBQ (divided into 3 separate 100 mg injections) once every 4 weeks • Hypereosinophilic syndrome ○ 300 mg SUBQ (divided into 3 separate 100 mg injections) once every 4 weeks
Adult Dose Adjustment Considerations	• Renal: 1. No dose adjustments provided in the manufacturer's labeling (not studied) 2. Renal dose adjustment unlikely to be necessary • Hepatic: 1. No dose adjustments provided in the manufacturer's labeling (not studied) 2. Hepatic dose adjustment unlikely to be necessary
Pediatric Patients	
Pediatric Pulmonary Indications & Dosing	• Severe asthma, maintenance therapy: 1. ≥6 years to 11 years: 40 mg SUBQ once every 4 weeks 2. ≥12 years: 100 mg SUBQ once every 4 weeks
Additional Pediatric Indications & Dosing	• Hypereosinophilic syndrome 1. ≥12 years: 300 mg SUBQ (divided into 3 separate 100 mg injections) once every 4 weeks
Pediatric Dose Adjustment Considerations	• Renal: 1. No dose adjustments provided in the manufacturer's labeling (not studied) 2. Renal dose adjustment unlikely to be necessary • Hepatic: 1. No dose adjustments provided in the manufacturer's labeling (not studied) 2. Hepatic dose adjustment unlikely to be necessary

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1. Mepolizumab. In: Lexi-Drugs. UpToDate Inc; 2025. Updated April 16, 2026. Accessed April 17, 2026. https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/5921559?cesid=6EQymyrRga0&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dnucala%26t%3Dname%26acs%3Dfalse%26acq%3Dnucala
2. Nucala (Mepolizumab). Prescribing information. GlaxoSmithKline, 2025. Accessed April 17, 2026. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Nucala/pdf/NUCALA-PI-PIL-IFU-COMBINED.PDF.

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Omalizumab

Biologic	omalizumab (Xolair®)
Overview	
Mechanism	• Anti IgE
Testing Required Before Start	• Confirm positive skin testing and/or allergen-specific IgE antibodies • Total IgE serum levels • Body weight • Treat any parasitic infections prior to initiating
Serious Side Effects	• Anaphylaxis (BBW) • Injection site reactions
Common Side Effects	• Injection site reactions, headache, arthralgia, pain, dizziness, pharyngitis/sinusitis, fever, peripheral edema, abdominal pain, fatigue, infections
Monitoring Parameters	• Observe 2 hours after first 3 injections for signs of anaphylaxis • Observe 30 minutes after all subsequent injections • Body weight • Signs of infection • Signs of vasculitis or hypereosinophilia
Available Product Formulations	Prefilled syringes (ages 1 year and up): 75 mg/0.5 mL, 150 mg/mL, 300 mg/2 mL Autoinjector (ages 12 years and up): 75 mg/0.5 mL, 150 mg/mL, 300 mg/2 mL Vial for reconstitution: 150 mg
Storage and Administration Information	• Store refrigerated, protect from light (may be at room temperature for up to 2 days) • Administer via SUBQ injection into the upper arm, thigh, or abdomen (avoid ~2 inches surrounding the navel) • Initiate in health care setting; health care provider to assess if appropriate for self or caregiver administration for future doses
Adult Patients	
Adult Pulmonary Indications & Dosing	Moderate-severe allergic asthma • Dose and frequency vary based on actual body weight and pre-treatment IgE levels, dose should be adjusted for significant changes in body weight but not based on changing IgE levels unless therapy is interrupted for >1 year. • Asthma: 150, 225, 300, or 375 mg SUBQ • Frequency: every 2-4 weeks • Check package insert for most up to date dosing.
Additional Adult Indications & Dosing	IgE mediated food allergy Chronic rhinosinusitis with nasal polyps: 75, 150, 225, 300, 375, 450, 525, 600 mg SUBQ Frequency: every 2-4 weeks Check package insert for most up to date dosing. Chronic spontaneous urticaria (not dependent on serum IgE or body weight):

	300 mg SUBQ every 4 weeks May also consider 150 mg SUBQ every 4 weeks but associated with decreased efficacy May consider increasing to 600 mg or decreasing dosing interval to 2 weeks if response is inadequate after 6 months
Adult Dose Adjustment Considerations	• Renal: o No dose adjustments recommended in the manufacturer's labeling (not studied) o Renal dose adjustment unlikely to be necessary • Hepatic: o No dose adjustments recommended in the manufacturer's labeling (not studied) o Hepatic dose adjustment unlikely to be necessary
Pediatric Patients	
Pediatric Pulmonary Indications & Dosing	Moderate-severe allergic asthma • Dose and frequency vary based on actual body weight and pre-treatment IgE levels, dose should be adjusted for significant changes in body weight but not based on changing IgE levels unless therapy is interrupted for >1 year. • Asthma, 6+ years: 75, 150, 225, 300, or 375 mg SUBQ • Frequency: every 2-4 weeks • Check package insert for most up to date dosing.
Additional Pediatric Indications & Dosing	IgE mediated food allergy, 1+ years: 75, 150, 225, 300, 375, 450, 525, 600 mg SUBQ Frequency: every 2-4 weeks Check package insert for most up to date dosing. Chronic spontaneous urticaria, 12+ years (not dependent on serum IgE or body weight): 150-300 mg SUBQ every 4 weeks
Pediatric Dose Adjustment Considerations	• Renal: o No dose adjustments recommended in the manufacturer's labeling (not studied) o Renal dose adjustment unlikely to be necessary • Hepatic: o No dose adjustments recommended in the manufacturer's labeling (not studied) o Hepatic dose adjustment unlikely to be necessary

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2. Xolair (omalizumab) [package insert]. South San Francisco, CA: Genentech, Inc; 2025. https://www.gene.com/download/pdf/xolair_prescribing.pdf

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Tezepelumab

Biologic	Tezepelumab (Tezspire)
Overview	
Mechanism	Thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody
Testing Required Before Start	Helminth infections; Avoid use of live attenuated vaccines
Serious Side Effects	Hypersensitivity reactions with anaphylaxis; Polysorbate 80 hypersensitivity reactions
Common Side Effects	Pharyngitis, arthralgia and back pain
Monitoring Parameters	Hypersensitivity reactions; FEV1, peak flow, PFTs, signs of infection; increased use of short-acting beta-2 agonist inhalers
Available Product Formulations	Available in prefilled pen or syringe, refrigeration required.
Storage and Administration Information	Allow to warm to room temperature for ~60 minutes prior to administration. Syringe is for HCP administration. Patient, caregiver or HCP may use pen for administration.
Adult Patients	
Adult Pulmonary Indications & Dosing	Severe asthma: 210mg SUBQ every 4 weeks
Additional Adult Indications & Dosing	Inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP): 210mg SUBQ every 4 weeks
Adult Dose Considerations	N/A
Pediatric Patients	
Pediatric Respiratory Indications & Dosing	Severe asthma: Children > or = 12 years old and adolescents: 210mg SUBQ every 4 weeks
Additional Pediatric Indications & Dosing	Inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP): 210mg SUBQ every 4 weeks
Pediatric Dose Considerations	N/A

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