American College of Allergy, Asthma & Immunology

Biologics at a Glance

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BRAND NAME Generic Name Manufacturer	ADBRY™ Tralokinumab-ldrm LEO Pharma, Inc.
Pharmacology	IL-13 antagonist monoclonal antibody (IgG4). Inhibits IL-13 signaling.
Indications	Treatment of moderate-to-severe atopic dermatitis in patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
Lab Requirements (Suggestions)	Peripheral eosinophil count prior to treatment.
Age	18+ yrs
Dose	**Adult patients 18+ years:** *Loading dose:* 600mg x1 (4 syringes or 2 auto-injectors). *Maintenance dose:* 300mg q2 weeks (2 syringes or 1 auto-injector). * For adult patients who achieve clear/almost clear skin after 16 weeks and weigh <100kg, a dosage of 300 mg every 4 weeks may be considered. **Pediatric patients 12-17 years:** *Loading dose:* 300mg x1 (2 syringes). *Maintenance dose:* 150mg q2 weeks (1 syringe).
How Supplied	**Syringe:** 150 mg/mL as a single dose for pediatric patients (12-17y) or adult patients (18y+). **Auto-Injector:** 300 mg/2 mL as a single dose for adult patients (18y+).
How to Prescribe	www.adbryhcp.com/support-and-resources
Considerations for Administration Protocols	Store refrigerated (36°F to 46°F) in original container to protect from heat, light. Allow 30 minutes (syringe) or 45 minutes (auto-injector) to reach room temperature without removing the needle cover or cap, respectively. Stable at room temp (up to 86°F) for up to 14 days; use or discard within this time. Do not re-refrigerate. Do not freeze. Do not shake. Do not expose to heat. Avoid use of live attenuated vaccines.
Side Effects	Most common (≥ 1%): URIs, conjunctivitis, injection site reactions, and eosinophilia.
Anti-drug antibody (ADA) formation	Across all trial periods, 4.6% of patients developed ADA; 1.0% had neutralizing ADA (NADA). In patients 12y+, NADA did not correlate with safety nor efficacy.
Practice Notes	
Special Populations	Pregnancy Registry: to enroll, visit mothertobaby.org/ongoing-study/adbry-tralokinumab/

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BRAND NAME Generic Name Manufacturer	CINQAIR Reslizumab Teva Respiratory, LLC
Pharmacology	IL-5 antagonist monoclonal antibody (IgG4κ). Inhibits IL-5 signaling.
Indications	Add-on maintenance treatment of patients 18 years and older with severe eosinophilic asthma.
Lab Requirements (Suggestions)	Peripheral eosinophil count prior to treatment; efficacy best with increased eosinophil count (ie, >300 cells/uL).
Age	18+ yrs
Dose	3 mg/kg IV q4 weeks; infuse over 20-50 minutes.
How Supplied	**Vial:** 100 mg/10 mL (10 mg/mL) as a single dose for IV use.
How to Prescribe	www.cinqairhcp.com/support/
Considerations for Administration Protocols	Do not administer as an IV push or bolus. Treat patients with pre-existing helminth infections before therapy.
Side Effects	Most common: (≥2%): oropharyngeal pain. Anaphylaxis occurred in 0.3% of patients in clinical studies.
Anti-drug Antibody (ADA) Formation	In patients with asthma 18+ years, neutralizing ADA were not evaluated.
Practice Notes	Store refrigerated (36°F to 46°F) in original package until time of use. Administer immediately after preparation. If not used immediately, store reconstituted solution in cool, dark place (36°F to 77°F) for up to 16 hours; use or discard within this time. Do not re-refrigerate. Do not freeze. Do not shake.
Special Populations	No pregnancy registry. No human data.

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BRAND NAME Generic Name Manufacturer	DUPIXENT Dupilumab Sanofi & Regeneron
Pharmacology	A monoclonal antibody that targets the interleukin-4 receptor alpha subunit (IL-4Rκ) and blocks the intercellular signaling of IL-4 and IL-13.
Indications	Moderate-to-severe atopic dermatitis; add-on maintenance treatment for moderate-to-severe eosinophilic asthma; OCS-dependent asthma of any severity; uncontrolled CRSwNP; eosinophilic esophagitis; prurigo nodularis.
Lab Requirements (Suggestions)	Asthma: Peripheral eosinophil count prior to treatment; efficacy best with increased eosinophil count (ie, >300 cells/uL).
Age	6+ mos for atopic dermatitis; 6+ yrs for eosinophilic/OCS-dependent asthma; 18+ yrs for CRSwNP or prurigo nodularis; 1+ yrs for EoE (must be >15kg).
Dose	For dose information, please consult the Prescribing Information at: www.regeneron.com/downloads/dupixent_fpi.pdf
How Supplied	**Single-dose pre-filled Syringe (6 mos+):** 300mg/2mL; 200 mg/1.14 mL. **Single-dose pre-filled Auto-Injector pen (2 yrs+):** 300mg/2mL; 200 mg/1.14 mL.
How to Prescribe	www.dupixentmyway.com
Considerations for Administration Protocols	• Home self-administration. • Treat patients with pre-existing helminth infections before therapy. • Shared decision-making is recommended when considering live vaccines. (https://www.annallergy.org/article/S1081-1206(24)00337-5/fulltext)
Side Effects	Injection site reactions are common; conjunctivitis, keratitis, arthralgia, peripheral eosinophilia.
Anti-drug Antibody (ADA) Formation	
Practice Notes	
Special Populations	Pregnancy Registry: to enroll, visit mothertobaby.org/ongoing-study/dupixent-dupilumab/.

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BRAND NAME Generic Name Manufacturer	FASENRA Benralizumab AstraZeneca
Pharmacology	IL-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1κ). Binds to alpha subunit of IL-5r. Inhibits IL-5 signaling and induces NK cell-mediated eosinophil apoptosis via antibody dependent cell-mediated cytotoxicity.
Indications	Add-on maintenance treatment of patients 6 years and older with severe eosinophilic asthma.
Lab Requirements (Suggestions)	Peripheral eosinophil count prior to treatment; efficacy best with increased eosinophil count (ie, >300 cells/uL).
Age	6+ yrs
Dose	**Patients 12y+:** 30 mg SQ q4 weeks x3, then q8 weeks. **Patients 6-11y:** *<35 kg:* 10 mg SQ q4 weeks x3, then q8 weeks. *35+ kg:* 30 mg SQ q4 weeks x3, then q8 weeks.
How Supplied	**Syringe:** 10 mg/0.5 mL as a single dose; 30 mg/mL as a single dose. **Auto-Injector:** 30 mg/mL as a single dose (FASENRA pen).
How to Prescribe	www.fasenrahcp.com/access-360
Considerations for Administration Protocols	Treat patients with pre-existing helminth infections before therapy.
Side Effects	Most common (≥5%): headache and pharyngitis.
Anti-drug Antibody (ADA) Formation	In patients with asthma 12+ years old, 12% of patients developed neutralizing ADA (NADA); this percentage was comparable in children 6-11y. NADA were associated with increased drug clearance and increased blood eosinophil levels. In patients with asthma 12+, NADA did not correlate with safety nor efficacy.
Practice Notes	Store refrigerated (36°F to 46°F) in original carton to protect from heat, light. Stable at room temp for up to 14 days; use or discard within this time. Do not re-refrigerate. Do not freeze. Do not shake. Do not expose to heat.
Special Populations	Pregnancy Registry exists but as of 6/2024 no longer enrolling patients.

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BRAND NAME Generic Name Manufacturer	NUCALA Mepolizumab GSK
Pharmacology	IL-5 antagonist monoclonal antibody (IgG1κ). Inhibits IL-5 signaling.
Indications	Add-on maintenance treatment of patients 6 years and older with severe eosinophilic asthma. Add-on maintenance treatment of patients 18 years and older with chronic rhinosinusitis with nasal polyps. Eosinophilic granulomatosis with polyangiitis (EGPA) in patients 18 years and older. Hypereosinophilic syndrome (for ≥6 months without an identifiable non-hematologic secondary cause) in patients 12 years and older.
Lab Requirements (Suggestions)	Peripheral eosinophil count prior to treatment; efficacy best with increased eosinophil count (ie, >300 cells/uL).
Age	6+ yrs for asthma; >18 yrs for EGPA and CRSwNP; 12+ yrs for HES.
Dose	**Asthma:** *Patients 6-11y:* 40 mg SQ q4 weeks. *Patients 12y+:* 100 mg SQ q4 weeks. **CRSwNP:** 100 mg SQ q4 weeks. **EGPA, HES:** 300 mg SQ q 4 weeks..
How Supplied	**Vial:** 100 mg as a single dose for in-office use. **Syringe:** 40 mg/0.4 mL as a single dose; 100 mg/mL as a single dose. **Auto-Injector:** 100mg/mL as a single dose (NUCALA pen).
How to Prescribe	nucalahcp.com/severe-eosinophilic-asthma/access/mynucala/
Considerations for Administration Protocols	Consider herpes zoster vaccination if appropriate. Treat patients with pre-existing helminth infections before therapy. For EGPA, HES: administer individual 100-mg injections ≥5 cm (≥2") apart.
Side Effects	Most common (≥5%): • Asthma: Headache, injection site reaction, back pain, and fatigue. • CRSwNP: Oropharyngeal pain and arthralgia. • EGPA and HES: Similar to asthma.
Anti-drug Antibody (ADA) Formation	In patients with asthma 12+ years old, <1% developed neutralizing ADA (NADA). NADA were not detected in children with asthma, nor adults with CRSwNP, EGPA, or HES. Anti-mepolizumab antibodies slightly increased (approximately 20%) the clearance of mepolizumab. There was no evidence of a correlation between anti-mepolizumab antibody titers and change in eosinophil level.
Practice Notes	Store refrigerated (Each vial should be used for a single patient, and any remaining contents should be discarded.) Just before administration, remove 1 mL of reconstituted NUCALA for injection. Do not shake the reconstituted solution during the procedure as this could lead to product foaming or precipitation. If the reconstituted solution is not used immediately, store below 30°C (86°F). Do not freeze. Discard if not used within 8 hours of reconstitution.
Special Populations	Pregnancy Registry exists but as of 6/2024 no longer enrolling patients.

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BRAND NAME Generic Name Manufacturer	TEZSPIRE Tezepelumab Amgen and AstraZeneca
Pharmacology	TSLP antagonist monoclonal antibody (IgG2κ). Inhibits TSLP signaling, decreasing release of downstream mediators.
Indications	Add-on maintenance treatment of patients12 years and older with severe asthma.
Lab Requirements (Suggestions)	Peripheral eosinophil count may be needed prior to treatment; efficacy best with increased eosinophil count (ie, >300 cells/uL).
Age	12+ yrs
Dose	210 mg SQ q4 weeks
How Supplied	**Vial:** 210 mg/1.91 mL (110 mg/mL) as a single dose for HCP administration. **Syringe:** 210 mg/1.91 mL (110 mg/mL) as a single dose for HCP administration. **Auto-Injector:** 210 mg/1.91 mL (110 mg/mL) solution as a single dose for self-administration (TEZSPIRE pen).
How to Prescribe	www.tezspirehcp.com/
Considerations for Administration Protocols	Store refrigerated (36°F to 46°F) in original container to protect from heat, light. Allow 60 minutes to reach room temperature. Stable at room temp for up to 30 days; use or discard within this time. Do not re-refrigerate. Do not freeze. Do not shake. Do not expose to heat. Avoid use of live attenuated vaccines.
Side Effects	Most common (≥ 3%): pharyngitis, arthralgia, back pain.
Anti-drug Antibody (ADA) Formation	In 2 trials, 5% of patients developed ADA; <1% had neutralizing ADA (NADA). NADA did not correlate with safety nor efficacy.
Practice Notes	
Special Populations	No pregnancy registry. No human data.

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BRAND NAME Generic Name Manufacturer	XOLAIR Omalizumab Genentech and Novartis Pharmaceuticals Corporation
Pharmacology	Inhibits the binding of IgE to the high-affinity IgE receptor (FcκRI) on the surface of mast cells and basophils.
Indications	Moderate to severe allergic asthma; refractory chronic spontaneous urticaria (CSU); uncontrolled CRSwNP; risk reduction in patients with IgE-mediated food allergy.
Lab Requirements (Suggestions)	Asthma: IgE 30-700; sensitization to perennial allergen.
Age	6+ yrs for asthma; 12+ yrs for CSU; 18+ yrs for CRSwNP; 1+ yrs for food allergy.
Dose	For dose information, please consult the Prescribing Information at: www.gene.com/download/pdf/xolair_prescribing.pdf
How Supplied	**Syringe:** 75 mg/0.5ml, 150 mg/ml, 300 mg/2 ml. **Vial:** 150 mg lyophilized powder in single-dose vial; requires reconstitution.
How to Prescribe	www.xolairhcp.com/
Considerations for Administration Protocols	• Strongly consider boxed warning regarding anaphylaxis and epinephrine Rx. • Some patients will quality for self-administration out-of-office. • Observation for 2 hours after the first 3 doses is recommended; consider 30-minute post-injection observation period thereafter (although some patients will qualify for self-administration out-of-office).
Side Effects	Injection site reactions are common; anaphylaxis has occurred, drug has boxed warning.
Anti-drug Antibody (ADA) Formation	
Practice Notes	
Special Populations	No increased rate of major birth defects or miscarriage with XOLAIR exposure during pregnancy (EXPECT study). There was an increased rate of low birth weight in infants exposed to Xolair; however women taking XOLAIR during pregnancy had more severe asthma, so it is difficult to determine whether the low birth weight was due to the drug or the asthma severity. (QECC study)

