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)	CBC w diff (peripheral absolute eosinophil count) prior to treatment.
Age	12+ 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	Approved for home self-administration. Store refrigerated (36°F to 46°F) in the 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.
Side Effects	**Most common (≥ 1%):** URIs, conjunctivitis, injection site reactions, and eosinophilia.
Practice Notes	Avoid use of live attenuated vaccines.
Special Populations	For information on pregnancy, 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	Treat patients with pre-existing helminth infections before therapy. NOT approved for home self-administration. Do not administer as an IV push or bolus. Store refrigerated (36°F to 46°F) in the 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.
Side Effects	Most common: (≥2%): oropharyngeal pain. Anaphylaxis occurred in 0.3% of patients in clinical studies.
Practice Notes	
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-4Rα) 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; chronic spontaneous urticaria; COPD; bullous pemphigoid.
Lab Requirements	Asthma: CBC w diff (peripheral absolute 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; 1+ yrs for EoE (must be >15kg); 12+ for CSU and CRSwNP; 18+ for COPD and bullous pemphigoid; 18+ yrs for prurigo nodularis.
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	https://www.dupixenthcp.com/patient-support/dupixent-myway
Considerations for Administration Protocols	Approved for home self-administration. Treat patients with pre-existing helminth infections before therapy. Dupixent is sterile and preservative-free. Discard any unused portion. Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.
Side Effects	Injection site reactions are common; conjunctivitis, keratitis, arthralgia, peripheral eosinophilia.
Practice Notes	Shared decision-making is recommended when considering live vaccines. (https://www.annallergy.org/article/S1081-1206(24)00337-5/fulltext)
Special Populations	For information on pregnancy, visit https://mothertobaby.org/fact-sheets/dupilumab-dupixent/.

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BRAND NAME Generic Name Manufacturer	EBGLYSS Lebrikizumab-ibkz Lilly, A Medicine Company
Pharmacology	IL-13 inhibitor, selectively binds to IL13, preventing formation of IL4-Rα/IL13Rα1.
Indications	Moderate to severe atopic dermatitis.
Lab Requirements (Suggestions)	NO lab monitoring.
Age	12yo + & weigh 40kg + moderate to severe atopic dermatitis.
Dose	250mg/2mL injection. 500 mg (two 250 mg injections) at Week 0 and Week 2, followed by 250 mg (one injection) every 2 weeks until Week 16 or later, when adequate clinical response is achieved. Maintenance dose is 250 mg every 4 weeks.
How Supplied	250mg/2mL subcutaneous injection. Prefilled pen or prefilled syringe.
How to Prescribe	https://uspl.lilly.com/ebglyss/ebglyss.html#pi
Considerations for Administration Protocols	Approved for home self-administration. Store refrigerated at 2°C to 8°C (36°F to 46°F). If necessary, EBGLYSS can be stored at room temperature up to 30°C (86°F) for up to 7 days in the original carton.
Side Effects	**Most common:** >1% conjunctivitis, injection site reactions, herpes zoster **Warnings:** hypersensitivity reaction, conjunctivitis, keratitis, parasitic infections, vaccinations. Contraindicated in patients with prior serious hypersensitivity to expipients of lebrikizumab-ibkz.
Practice Notes	NO boxed warning. Avoid use of live vaccines immediately prior to or during treatment. No data available on response to live vaccines. Complete all age-appropriate vaccinations according to current immunization guidelines prior to initiating treatment.
Special Populations	

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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. Eosinophilic granulomatosis with polyangiitis (EGPA) in patients 18 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 eosinophilic asthma; >=18 yrs for EGPA
Dose	**Asthma Patients 12y+:** 30 mg SQ q4 weeks x3, then q8 weeks. **Asthma 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. **EGPA:** 30 mg SQ q 4 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	Approved for home self-administration. Treat patients with pre-existing helminth infections before therapy. 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.
Side Effects	Most common (≥5%): headache and pharyngitis.
Practice Notes	
Special Populations	For information on pregnancy, visit https://mothertobaby.org/fact-sheets/benralizumab/.

BRAND NAME Generic Name Manufacturer	NEMLUVIO Nemolizumab-ilto Galderma Laboratories
Pharmacology	Humanized IgG2 monoclonal antibody that inhibits IL-31 signaling by binding selectively to IL-31 RA. Inhibits IL-31 induced responses including the release of proinflammatory cytokines and chemokines.
Indications	Moderate to severe atopic dermatitis. Treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies. Prurigo Nodularis.
Lab Requirements (Suggestions)	None
Age	12yo + & weigh 40kg + moderate to severe atopic dermatitis.
Dose	**Atopic dermatitis:** 60 mg (2x 30mg) loading dose. 30mg q4 weeks maintenance dose, if clear skin after 16wks, can space q 8 wks. **Prurigo Nodularis:** *<90kg:* loading dose 60 mg (two 30 mg injections), followed by 30 mg given q 4 weeks. *>90kg:* loading dose 60 mg (two 30 mg injections), followed by 60 mg q4 weeks.
How Supplied	Prefilled pen subcutaneous injection.
How to Prescribe	https://www.nemluvio.com/
Considerations for Administration Protocols	Approved for home self-administration. May be stored at room temperature up to 77° F (25°C) for up to 90 days. Easy to take on the go.
Side Effects	**Most common:** headache (5%), arthralgia, myalgia, urticaria (1%).
Practice Notes	Low injection site reactions 1%. Relieves itch as soon as 48 hrs.
Special Populations	Safety unknown for breastfeeding and pregnancy. No pregnancy registry available.

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. Add-on maintenance treatment for adults with inadequately controlled COPD and an eosinophilic phenotype.
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	Approved for home self-administration. Treat patients with pre-existing helminth infections before therapy. 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.
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.
Practice Notes	Consider herpes zoster vaccination if appropriate. For EGPA, HES: administer individual 100-mg injections ≥5 cm (≥2") apart.
Special Populations	For information on pregnancy, visit mothertobaby.org/fact-sheets/mepolizumab/.

BRAND NAME Generic Name Manufacturer	TEZSPIRE Tezepelumab-ekko Amgen and AstraZeneca
Pharmacology	TSLP antagonist monoclonal antibody (IgG2κ). Inhibits TSLP signaling, decreasing release of downstream mediators.
Indications	Add-on maintenance treatment of patients 12 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	Avoid use of live attenuated vaccines. 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.
Side Effects	Most common (≥ 3%): pharyngitis, arthralgia, back pain.
Practice Notes	
Special Populations	No pregnancy registry. No human data.

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BRAND NAME Generic Name Manufacturer	XOLAIR Omalizumab Genentech, a Member of the Roche Group 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	Approved for home self-administration. Boxed warning regarding anaphylaxis and epinephrine Rx. Observation for 2 hours after the first 3 doses is recommended; consider a 30-minute post-injection observation period thereafter when in office. Persons with latex allergies should not handle XOLAIR prefilled syringe because the needle cap of the XOLAIR 75 mg/0.5 mL and 150 mg/mL prefilled syringes contains a derivative of natural rubber latex. Use the XOLAIR solution within 8 hours following reconstitution when stored in the vial at 2°C to 8°C (36°F to 46°F), or within 4 hours of reconstitution when stored at room temperature. Reconstituted XOLAIR vials should be protected from sunlight.
Side Effects	Injection site reactions are common; anaphylaxis has occurred (boxed warning).
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)

