Biologics at a Glance

BRAND NAME Generic Name Manufacturer	NUCALA Mepolizumab GSK	CINQAIR Reslizumab Teva	FASENRA Benralizumab AstraZeneca
Pharmacology	Binds to IL-5– inhibiting the bioactivity of IL-5 by blocking its binding to the alpha chain of the IL-5 receptor complex expressed on the eosinophil cell surface.	Binds to IL-5– inhibiting the bioactivity of IL-5 by blocking its binding to the alpha chain of the IL-5 receptor complex expressed on the eosinophil cell surface.	Binds to alpha subunit of IL-5 receptor on eosinophils, blocking action of IL-5, and induces apoptosis of eosinophils through interaction with NK cells by antibody-dependent cell-mediated cytotoxicity.
Indications	Add on maintenance therapy of patients with severe asthma with an eosinophilic phenotype. Eosinophilic Granulomatosis with Polyangiitis (EGPA) in adults. Hyper eosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause.	Severe asthma with an eosinophilic phenotype	Severe asthma with an eosinophilic phenotype
Lab Requirements (Suggestions)	Consider herpes zoster vaccination if medically appropriate vaccination, Eos > 150 within last 6 weeks or 300 within the past 12 months.	Eos > 400	CBC– No specific range for eosinophil count, but evidence of efficacy exists for eosinophil counts over 150 per microliter.
Age	6+ yrs for asthma; >18 yrs for EGPA; 12+ yrs for HES	18 and older	12 and older
Dose	40 mg SQ (6-11 yrs), 100 mg SQ (12+ yrs) every 4 weeks for asthma; EGPA and HES: 300 mg administered once every 4 weeks by subcutaneous injection as 3 separate 100-mg injections into the upper arm, thigh, or abdomen.	3 mg/kg IV Q 4 weeks infused over 20-50 minutes.	30 mg Q 4 weeks x 3 doses then Q 8 weeks.
How Supplied	100 mg vial (in-office, needs reconstitution), 100 mg pre-filled syringe (home use), 100 mg pre-filled autoinjector.	100 mg/10 ml vials	30 mg prefilled syringe or 30 mg pre-filled autoinjector "pen".
How to Prescribe	Fill out the enrollment form/ application, which includes the prescription, and send to Gateway to Nucala. Gateway will verify benefits, give name of specialty pharmacy to use and if a PA is needed. Can be enrolled using the online portal.	Fill out the enrollment form/ application, which includes the prescription, and send to Teva Support Solutions. Teva Support Solutions will verify benefits, give name of specialty pharmacy to use and if a PA is needed.	Fill out the enrollment form/ application, which includes the prescription, and send to Access360. Access360 will verify benefits, give name of specialty pharmacy to use and if a PA is needed. Can be enrolled using the online portal.
Considerations for Administration Protocols	• Home self-administration. • Proof of Zoster Vaccine. • Treat patients with pre-existing helminth infections before therapy.	• Given at an infusion center. • Treat patients with pre-existing helminth infections before therapy.	• Treat patients with pre-existing helminth infections before therapy. • 30 minute wait after injection from first dose.
Side Effects	Injection site reactions.	Anaphylaxis	Injection site reactions were similar to placebo: 2.2% vs 1.9%, respectively.
Practice Notes			

American College of Allergy, Asthma & Immunology

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Biologics at a Glance *(continued)*

American College of Allergy, Asthma & Immunology

BRAND NAME Generic Name Manufacturer	XOLAIR Omalizumab Genentech/Novartis	DUPIXENT Dupilumab Sanofi Genzyme/Regeneron
Pharmacology	Inhibits the binding of IgE to the high-affinity IgE receptor (FcεRI) on the surface of mast cells and basophils. Reduction in surface bound IgE on FcεRI-bearing cells limits the degree of release of mediators of the allergic response.	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 asthma and chronic Idiopathic urticaria (CIU) and uncontrolled nasal polyps (NP).	Moderate/severe uncontrolled atopic dermatitis; moderate/severe uncontrolled eosinophilic or OCS-dependent asthma; uncontrolled chronic rhinosinusitis w/ nasal polyps; eosinophilic esophagitis.
Lab Requirements (Suggestions)	*Asthma*– IgE > or =30; positive blood or skin test to perennial allergen. *CIU*– 6 weeks of uncontrolled hives with antihistamines. *NP:* No labs required prior to prescribing. Inadequate response to intranasal corticosteroids.	*Atopic Dermatitis:* No lab requirements needed before prescribing. *Asthma:* CBC – No specific range for eosinophil count, but evidence of efficacy exists for eosinophil counts over 150 per microliter. *CRSwNP:* No labs required prior to prescribing. *Eosinophilic esophagitis:* No labs required prior to prescribing.
Age	6+ yrs for asthma; 12+ yrs for CIU; 18+ yrs for NP.	6+ yrs for atopic dermatitis; 6+ yrs for asthma; 18+ yrs for CRSwNP; 12+ yrs weighing at least 40 kilograms (about 88 lbs) for EOE.
Dose	*Asthma:* 75 to 375 mg SC every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). *CIU:* 150mg or 300mg subq every 4 weeks. *NP:* 75 to 600 mg SC every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL) measured before the start of treatment, and body weight (kg). Administer in a healthcare provider's office or home.	For dose information, please consult the Package Insert at https://www.regeneron.com/downloads/dupixent_fpi.pdf
How Supplied	150mg vial and 75 mg/0.5ml and 150 mg/ ml pre-filled syringe.	300mg/2mL pre-filled syringe with needle shield; 200 mg/1.14 mL solution in a single-dose pre-filled syringe with needle shield; 300mg/2mL pre-filled pen; 200 mg/1.14 mL pre-filled pen.
How to Prescribe	Fill out the enrollment form/ application, which includes the prescription, and send to Access Solutions. Access Solutions will verify benefits, give name of specialty pharmacy to use and if a PA is needed. Can be enrolled using the online portal.	Fill out the enrollment form/application, which includes the prescription, and send to Dupixent My Way and the Specialty pharmacy. The specialty pharmacy will verify benefits, whether a PA is needed, and will help with denials.
Considerations for Administration Protocols	• Autoinjectable epinephrine • Home self-administration. • Remove from refrigerator 30 minutes prior to appointment for mixing. • Wait times for office administration: Asthma – first 3 doses/appointments there is a 2 hour wait and then 30 minutes thereafter. • Urticaria – 30 minute wait after injections from first dose.	• Home self-administration. • Avoid live vaccines; Treat patients with pre-existing helminth infections before therapy.
Side Effects	Injection site reactions are common; anaphylaxis (patients with a history of anaphylaxis are at most risk of anaphylaxis).	*Both:* injection site reactions are common; hypersensitivity *Atopic Dermatitis:* conjunctivitis and keratitis *CRSwNP:* eosinophilia
Practice Notes		

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Biologics at a Glance *(continued)*

American College of Allergy, Asthma & Immunology

BRAND NAME Generic Name Manufacturer	TEZSPIRE Tezepelumab AstraZeneca and Amgen	ADBRY™ Tralokinumab-ldrm LEO Pharma
Pharmacology	A human monoclonal antibody that blocks thymic stromal lymphopoietin (TSLP) and thus inhibits TSLP signaling through the TSLP receptor complex.	A human IgG4 monoclonal antibody that specifically binds to interleukin-13 and inhibits its interaction with the IL-13 receptor.
Indications	1) Add-on maintenance of severe uncontrolled asthma with no phenotype or biomarker limitations. Note: NOT indicated for relief of acute bronchospasm or status asthmaticus.	Treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Can be used along with topical steroids and calcineurin inhibitors.
Lab Requirements (Suggestions)	*Asthma:* None.	None required, but consider a CBC as peripheral eosinophilia has been reported with tralokinumab. Evaluate for parasitic infections if indicated. Treat patients with pre-existing helminth infections before initiating treatment.
Age	12+ yrs for asthma.	18 and older
Dose	*Asthma:* 210 mg administered subcutaneously once every 4 weeks.	Initial dose of 600mg subcutaneous injection (4 prefilled syringes) followed by 300mg SC (2 prefilled syringes) every other week. A dosage of 300 mg every 4 weeks may be considered for patients below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment.
How Supplied	210 mg/1.91 mL solution in a single-dose glass vial; 210 mg/1.91 mL solution in a single-dose pre-filled syringe.	Injection: 150 mg/mL solution in a single-dose prefilled syringe with needle guard.
How to Prescribe	Fill out enrollment form and fax to 1-888-388-6016. Call Tezspire Together program for info (1-888-TZSPIRE / 897-7473). https://www.tezspirehcp.com/	Prescriber and support enrollment forms available at www.adbry.com.
Considerations for Administration Protocols	• Tezspire is intended for administration by a healthcare provider. • Store refrigerated between 36F and 46F (2C - 8C). • Remove from refrigerator and allow it to reach room temp (~60 minutes). • Can be kept at room temperature (68-77F or 20-25 C for a maximum of 30 days). Do not re-refrigerate. • Avoid live attenuated vaccines as this has not been evaluated.	• Before injection, remove ADBRY prefilled syringes from the refrigerator and allow to reach room temperature (30 minutes for the 150 mg/mL prefilled syringes) without removing the needle cap. • After removal from the refrigerator, prefilled syringes may be kept at room temperature up to 30°C (86°F) and must be used within 14 days or discarded.
Side Effects	Injection site reactions; hypersensitivity; Most common adverse reactions: pharyngitis, arthralgia, back pain.	Most common adverse reactions (incidence ≥ 1%) are upper respiratory tract infections, conjunctivitis, injection site reactions, and eosinophilia. Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with use of tralokinumab. Conjunctivitis and keratitis have been reported.
Practice Notes		