

# 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	<ul style="list-style-type: none"> <li>• Home self-administration.</li> <li>• Proof of Zoster Vaccine.</li> <li>• Treat patients with pre-existing helminth infections before therapy.</li> </ul>	<ul style="list-style-type: none"> <li>• Given at an infusion center.</li> <li>• Treat patients with pre-existing helminth infections before therapy.</li> </ul>	<ul style="list-style-type: none"> <li>• Treat patients with pre-existing helminth infections before therapy.</li> <li>• 30 minute wait after injection from first dose.</li> </ul>
Side Effects	Injection site reactions.	Anaphylaxis	Injection site reactions were similar to placebo: 2.2% vs 1.9%, respectively.
Practice Notes			

## Biologics at a Glance *(continued)*

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 signalling 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.
Lab Requirements (Suggestions)	<i>Asthma</i> - IgE > or =30; positive blood or skin test to perennial allergen. <i>CIU</i> - 6 weeks of uncontrolled hives with antihistamines. <i>NP</i> : No labs required prior to prescribing. Inadequate response to intranasal corticosteroids.	<i>Atopic Dermatitis</i> : No lab requirements needed before prescribing. <i>Asthma</i> : CBC - No specific range for eosinophil count, but evidence of efficacy exists for eosinophil counts over 150 per microliter. <i>CRSwNP</i> : No labs required prior to prescribing..
Age	6+ yrs for asthma; 12+ yrs for CIU; 18+ yrs for NP.	6+ yrs for atopic dermatitis; 12+ yrs for asthma; 18+ yrs for CRSwNP.
Dose	<i>Asthma</i> : 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). <i>CIU</i> : 150mg or 300mg subq every 4 weeks. <i>NP</i> : 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.	<i>Atopic Dermatitis</i> : Initial Dose: 600 mg subq; Subsequent Doses: 300 mg subq every 2 weeks. <i>Asthma</i> : Initial dose of 400 mg (two 200 mg injections) followed by 200 mg given every other week OR an initial dose of 600 mg (two 300 mg injections) followed by 300 mg given every other week OR for patients requiring concomitant oral corticosteroids or with co-morbid moderate-to-severe atopic dermatitis for which dupilumab is indicated, start with an initial dose of 600 mg followed by 300 mg given every other week. <i>CRSwNP</i> : Initial and maintenance dose of 300 mg SQ every 2 weeks; NO loading dose.
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	<ul style="list-style-type: none"> <li>• Autoinjectable epinephrine</li> <li>• Home self-administration.</li> <li>• Remove from refrigerator 30 minutes prior to appointment for mixing.</li> <li>• Wait times for office administration: Asthma - first 3 doses/appointments there is a 2 hour wait and then 30 minutes thereafter.</li> <li>• Urticaria - 30 minute wait after injections from first dose.</li> </ul>	<ul style="list-style-type: none"> <li>• Home self-administration.</li> <li>• Avoid live vaccines; Treat patients with pre-existing helminth infections before therapy.</li> </ul>
Side Effects	Injection site reactions are common; anaphylaxis (patients with a history of anaphylaxis are at most risk of anaphylaxis).	<i>Both</i> : injection site reactions are common; hypersensitivity <i>Atopic Dermatitis</i> : conjunctivitis and keratitis <i>CRSwNP</i> : eosinophilia
Practice Notes		