WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 1/1/22 – 1/31/22

FDA Drug Safety Communications & Drug Information Updates:

Pfizer-BioNTech COVID-19 Vaccine Use Expanded 1/3/22

The FDA amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine to expand use of a single booster dose to include individuals 12 through 15 years of age, shorten the time between completion of the primary vaccination and a booster dose to at least 5 months for individuals 12 years and older, and allow for a third primary series dose for certain immunocompromised children 5 through 11 years of age.

Moderna COVID-19 Vaccine Booster Interval Shortened 1/7/22

The FDA amended the EUA for the Moderna COVID-19 vaccine to shorten the time between completion of the primary vaccination and a booster dose to at least 5 months for individuals 18 years of age and older.

Stop Using LuSys Laboratories COVID-19 Tests – FDA Safety Communication 1/11/22

The FDA warned people to stop using LuSys Laboratories COVID-19 Antigen Test and LuSys Laboratories COVID-19 IgG/IgM Antibody Test as the performance of these tests has not been established and the FDA suspects there is a high risk of false results. Neither test has been authorized or approved by the FDA. These tests may also be marked under the company names Luscient Diagnostics or Vivera Pharmaceuticals, or with the trade name EagleDx.

Buprenorphine Medicines Dissolved in the Mouth: Drug Safety Communication – Dental Problems 1/12/22

The FDA warned that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth to treat opioid use disorder and pain. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues. Despite this, the benefits of buprenorphine clearly outweigh the risks. Patients should be advised about the potential for dental problems and take extra steps after the medication has dissolved, including gently rinsing their teeth and gums with a large sip of water and swallow, and waiting at least one hour before brushing their teeth after use of the product.

Remdesivir EUA Revised for Pediatric Patients 1/21/22

The FDA revised the EUA for remdesivir to authorize use for treatment of pediatric patients weighing 3.5 kg to less than 40 kg or pediatric patients less than 12 years of age weighing at least 3.5 kg, with positive results of direct SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death. The EUA authorizes use of remdesivir via intravenous infusion for a total of 3 days for the treatment of mild-to-moderate disease.

FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant 1/24/22

The FDA revised the EUAs for bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab) due to data showing they are highly unlikely to be active against the omicron variant to limit use only to patients who are likely to have been infected with or exposed to a variant that is susceptible to these treatments. These treatments are not authorized for use in any U.S. states, territories, and jurisdictions at this time as the omicron variant is circulating at a very high frequency throughout the United States. In the future, if patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to these treatments, then use of these treatments may be authorized in those regions.

Spikevax (COVID-19 vaccine, mRNA) by Moderna: Second COVID-19 Vaccine FDA-Approved 1/31/22
The FDA has approved a second COVID-19 vaccine, the Moderna COVID-19 Vaccine; the approved vaccine will be marketed as Spikevax for the prevention of COVID-19 in individuals 18 years of age and older. Spikevax can be used interchangeably with the EUA Moderna COVID-19 Vaccine to provide the COVID-19 vaccination series. Moderna COVID-19 Vaccine remains available under EUA as a two-dose primary series for individuals 18 years of age and older, as a third primary series dose for individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose for individuals 18 years of age and older at least five months after completing a primary series of the vaccine. It is also authorized for use as a heterologous ("mix and match") single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different available COVID-19 vaccine.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch:

Angel Formula Infant Formula, by Moor Herbs: Recall – Possible Health Risks 1/10/22
Moor Herbs recalled Angel Formula after FDA testing found the product contained iron, sodium, and potassium content exceeding the maximum allowed and did not contain vitamin D.

Metformin HCl Extended-Release Tablets, USP 750 mg by Viona Pharmaceuticals: Recall – Detection of N-Nitrosodimethylamine (NDMA) Impurity 1/12/22
Viona Pharmaceuticals recalled 23 lots of Metformin HCL Extended-Release Tablets, USP 750 mg to the consumer level due to detection of NDMA impurity in one lot of the product. The product was manufactured by Cadila Healthcare for distribution by Viona Pharmaceuticals. The affected lot numbers and expiration dates can be found at the FDA website.

Senna Syrup 8.8 mg/5 mL by Lohxa LLC: Recall – Microbial Contamination 1/12/22
Lohxa LLC recalled one lot of Senna Syrup 8.8 mg/5 mL unit-dose cups (NDC 50268-731-24, lot AM1115S, expiration date 01/2023) to the consumer level due to potential microbial contamination. The product was distributed to AvKare (wholesaler) who may have further distributed product to clinics, hospitals, and healthcare providers labeled with the AVpak or AvKare name.

Semglee (Insulin Glargine Injection) by Mylan: Recall – Missing Label 1/19/22
Mylan recalled one batch of its non-interchangeable Semglee (insulin glargine injection) (NDC 49502-0196-75; Batch BF200003118; expiry August 2022), 100 units/ml (U-100), 3mL prefilled pens, packaged in a carton of five pens, due to the potential for the label to be missing on some prefilled pens inside the labelled carton.

RevitaDerm Wound Care Gel by Blaine Labs: Recall – Bacterial Contamination 1/27/22
Blaine Labs recalled one lot of RevitaDerm Wound Care Gel to the consumer level because a bottle has been found to be contaminated with *Bacillus cereus*. The product is packaged in either a 1 oz bottle or a 3 oz tube with lot number BL2844 and expiration date of 02/19/2023.

Polymyxin B for Injection, USP, 500,000 Unit per Vial by AuroMedics Pharma LLC: Recall – Presence of Particulate Matter 1/28/22
AuroMedics Pharma LLC recalled one lot of Polymyxin B for Injection USP, 500,000 Units/Vial (NDC 55150-234-10; lot CPB200013; expiration: 09/2022), to the consumer level due to a product complaint of the presence of particulate matter, identified as hair, discovered in a vial within this lot.

CovClear and ImmunoPass COVID-19 Tests by Empowered Diagnostics, LLC: Recall – Unauthorized 1/28/22
Empowered Diagnostics recalled all lots of the CovClear COVID-19 Rapid Antigen Test and ImmunoPass COVID-19 Neutralizing Antibody Rapid Test. These tests were distributed with labeling indicating they are authorized by the FDA, but neither test has been authorized, cleared, or approved for distribution or use by the FDA. The FDA issued a warning advising people to stop using these tests due to concern about the potentially higher risk of false results when using unauthorized tests.

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding undeclared active ingredients or contaminants in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Undeclared Ingredient(s) or Contaminants***
Artri Ajo King tablets	Joint pain/arthritis	Diclofenac
GAT Sport Jetfuel Diuretic*	Diuretic	Milk
Hard Dawn Rise and Shine capsules*	Male sexual enhancement	Tadalafil
Tawon Liar	Pain, rheumatism, insomnia, energy, immune system improvement, lowering cholesterol	Meloxicam

*recalled

New Product Shortages	***Date Initially Posted***
Metronidazole injection	1/13/22
Dextrose 50% injection	1/13/22
Cefixime oral capsules	1/21/22

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Daridorexant / Quviviq / Idorsia Pharmaceuticals	Orexin receptor antagonist for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	1/7/22
Abrocitinib / Cibinqo / Pfizer	Janus kinase inhibitor for the treatment of adults with refractory moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.	1/14/22
Tebentafusp-tebn / Kimmtrak / Immunocore	Bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.	1/25/22
Faricimab-svoa / Vabysmo / Genentech	VEGF and angiopoietin-2 inhibitor for the treatment of patients with neovascular (wet) age-related macular degeneration and diabetic macular edema.	1/28/22
COVID-19 vaccine, mRNA / Spikevax / Moderna	For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years and older.	1/31/22

New Indications:	***Description***	***Date Approved***
Upadacitinib / Rinvoq / AbbVie	For the treatment of moderate to severe atopic dermatitis in patients 12 years and older whose disease is not adequately controlled with other systemic therapies, including biologics, or when use of those therapies is not recommended.	1/14/22
Risankizumab-rzaa / Skyrizi / Abbvie	For the treatment of adults with active psoriatic arthritis	1/21/22
Remdesivir / Veklury / Gilead Sciences	For adults and pediatric patients (12 years of age and older who weigh at least 40 kilograms, which is about 88 pounds) with positive results of direct SARS-CoV-2 viral testing, who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.	1/21/22
von Willebrand factor (recombinant) / Vonvendi / Takeda	For routine prophylaxis to reduce the frequency of bleeding episodes in adults with severe Type 3 von Willebrand disease receiving on-demand therapy.	1/31/22

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Olopatadine HCl and mometasone furoate monohydrate / Ryaltris / Hikma Specialty	Nasal spray: 665 mcg olopatadine and 25 mcg mometasone furoate in each spray, metered-dose spray pump unit delivering 240 metered sprays and up to 6 priming sprays; for the treatment of symptoms of seasonal allergic rhinitis in adults and pediatric patients 12 years and older	1/13/22
Daptomycin / Dapzura RT / Baxter	For injection: 500 mg lyophilized powder for reconstitution in a single-dose vial; for treatment of complicated skin and skin structure infections, bacteremia, and endocarditis	1/25/22
Citalopram / Citalopram / Almatica	Oral capsules: 30 mg; for the treatment of major depressive disorder	1/31/22

Compiled by:

Terri Levien, Pharm.D.
Regan Smith, Pharm.D., PGY1 Drug Information Resident
Puneet Kaur, Doctor of Pharmacy Candidate 2022

Drug Information Center
College of Pharmacy and Pharmaceutical Sciences
Washington State University
412 E. Spokane Falls Blvd.
Spokane, WA 99202-2131
(509) 358-7662
Pharmacy.druginfo@wsu.edu

Daridorexant / *Quviviq* / Idorsia Pharmaceuticals	
Generic Name / Brand Name / Company	Daridorexant / *Quviviq* / Idorsia Pharmaceuticals
Date of approval	1/7/22
Drug Class (Mechanism of Action if novel agent)	Orexin receptor antagonist
Indication	For the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
Comparative agent – Therapeutic interchange?	Lemborexant, Suvorexant
Dosage forms/strengths.	Tablets: 25 mg, 50 mg
Common Dose/sig	25 to 50 mg once per night, taken orally 30 minutes before going to bed, with at least 7 hours remaining prior to planned awakening.
DEA Schedule	Pending
Date of market availability	May 2022
Similar Medication Names	Qulipta
Clinical Use Evaluation	
Common Adverse Effects	≥2% and greater than placebo: headache, somnolence or fatigue, dizziness, nausea
Severe Adverse Effects	CNS depression and daytime impairment; worsening of depression or suicidal ideation; sleep paralysis, hypnagogic/hypnopompic hallucinations, and cataplexy-like symptoms; complex sleep behaviors; compromised respiratory function.
Severe Drug-Drug Interactions	Strong CYP3A4 inhibitors: avoid concomitant use. Moderate CYP3A4 inhibitors: maximum recommended dose is 25 mg. Moderate or strong CYP3A4 inducers: avoid concomitant use. Alcohol and other concomitant CNS depressants: avoid concomitant use.
Severe Drug-Food Interactions	Time to sleep onset may be delayed if taken with or soon after a meal.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and effectiveness not established
Renal or Hepatic Dosing	Maximum recommended dosage is 25 mg nightly in moderate hepatic impairment. Use is not recommended in severe hepatic impairment. No adjustments required in renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: narcolepsy Warnings and precautions: CNS depressant effects and daytime impairment; worsening of depression/suicidal ideation; sleep paralysis, hypnagogic/hypnopompic hallucinations, and cataplexy-like symptoms; complex sleep behaviors; compromised respiratory function; need to evaluate for comorbid diagnoses if insomnia persists after 7 to 10 days.
Special administration technique or considerations	Take within 30 minutes of going to bed with at least 7 hours remaining prior to planned awakening; time to sleep onset may be delayed if taken with or soon after a meal.
Prepared by	Regan Smith
Source	Quviviq (daridorexant) [prescribing information]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; January 2022.

Abrocitinib / Cibinqo / Pfizer	
Generic Name / Brand Name / Company	Abrocitinib / Cibinqo / Pfizer
Date of approval	1/14/22
Drug Class (Mechanism of Action if novel agent)	Janus kinase (JAK) inhibitor
Indication	For the treatment of adults with refractory moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.
Comparative agent – Therapeutic interchange?	Baricitinib, tofacitinib, upadacitinib
Dosage forms/strengths.	Oral tablets: 50 mg, 100 mg, and 200 mg.
Common Dose/sig	Recommended starting dose is 100 mg by mouth once daily; may increase to 200 mg daily if no response is achieved by 12 weeks.
DEA Schedule	None
Date of market availability	March 2022
Similar Medication Names	Baricitinib
Clinical Use Evaluation	
Common Adverse Effects	≥2% and greater than placebo: nasopharyngitis, nausea, headache, herpes simplex, increased blood creatinine phosphokinase, dizziness, urinary tract infection, acne, and vomiting.
Severe Adverse Effects	Serious infections, herpes zoster, malignancy, thrombosis, major cardiovascular events, thrombocytopenia, lymphopenia, lipid elevations, retinal detachment.
Severe Drug-Drug Interactions	Use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants is not recommended; may be used with concomitant topical corticosteroids. Strong CYP2C19 inhibitors: dose reduction of abrocitinib recommended. Moderate-to-strong inhibitors of both CYP2C19 and CYP2C9: avoid concomitant use. Strong CYP2C19 or CYP2C9 inducers: avoid concomitant use.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Tuberculosis screening, viral hepatitis screening, complete blood count, lipid panel
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	Mild renal impairment: no recommended dose adjustments. Moderate renal impairment: recommended starting dose is 50 mg once daily; may increase to 100 mg if no response is achieved by 12 weeks. Severe renal impairment/end-stage renal disease: use not recommended. Mild or moderate hepatic impairment: no recommended dose adjustments. Severe hepatic impairment: use not recommended.

Abrocitinib continued…	
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Concomitant antiplatelet therapy (except for aspirin 81 mg daily) during the first 3 months of treatment. Warnings and precautions: Serious infections: avoid use in patients with active, serious infection including localized infection. Consider risks and benefits in patients with history or risk factors of serious infection. Screen for tuberculosis and hepatitis B infection prior to initiating therapy. Mortality: consider risks and benefits for individual patients prior to initiating or continuing therapy. Malignancy and lymphoproliferative disorders: perform periodic skin assessments in patients at increased risk of skin cancer. Consider risks and benefits for individual patients prior to initiating or continuing therapy. Major adverse cardiovascular events: consider risks and benefits for individual patients prior to initiating or continuing therapy, particularly in patients with risk factors. Discontinue therapy in patients who experience a myocardial infarction or stroke. Thrombosis: avoid use in patients at increased risk of thrombosis. Discontinue if symptoms of thrombosis occur and evaluate and treat patients appropriately. Laboratory abnormalities: evaluate complete blood counts prior to initiation, 4 weeks after initiation, and 4 weeks after a dose increase. Discontinuation is recommended for certain laboratory abnormalities. Assess lipid panel 4 weeks after initiation and treat any abnormalities according to clinical guidelines. Immunizations: all age-appropriate vaccinations should be completed prior to initiating therapy. Avoid live vaccinations immediately prior to, during, and immediately after therapy.
Special administration technique or considerations	Administer at approximately the same time each day, with or without food. Swallow tablets whole; do not crush, split, or chew tablets.
Prepared by	Regan Smith
Source	Abrocitinib (Cibinqo) [prescribing information]. New York, NY: Pfizer Labs; January 2022.

Tebentafusp-tebn / Kimmtrak / Immunocore	
Generic Name / Brand Name / Company	Tebentafusp-tebn / Kimmtrak / Immunocore
Date of approval	1/25/22
Drug Class (Mechanism of Action if novel agent)	Bispecific gp100 peptide-HLA-directed CD3 T-cell engager
Indication	Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Injection: 100 mcg/0.5 mL solution in a single-dose vial
Common Dose/sig	20 mcg intravenously on day 1, 30 mcg intravenously on day 8, 68 mcg intravenously on day 15, and 68 mcg intravenously once every week thereafter
DEA Schedule	None
Date of market availability	February 2022
Similar Medication Names	None
Clinical Use Evaluation	
Common Adverse Effects	>30%: cytokine release syndrome, rash, pyrexia, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, vomiting; lab abnormalities occurring in >50%: decreased lymphocyte count, increase creatinine, increased glucose, increased AST, increased ALT, decreased hemoglobin, decreased phosphate
Severe Adverse Effects	Cytokine Release Syndrome (CRS)
Severe Drug-Drug Interactions	Elevation of certain proinflammatory cytokines may suppress CYP450 enzyme activities.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy test; ALT, AST, and total blood bilirubin;
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	Dosage adjustments recommended in patients developing grade 3 or 4 elevated liver enzymes. No adjustments in mild to moderate renal impairment or mild hepatic impairment. Has not been studied in severe renal impairment or moderate to severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings: Cytokine Release Syndrome, skin reactions (rash, pruritus, and cutaneous edema) and elevated liver enzymes (ALT, AST and bilirubin). May cause fetal harm; use effective contraception during treatment and for 1 week after the last dose.
Special administration technique or considerations	Infuse diluted solution over 15-20 minutes through a dedicated line with a 0.2 micron in-line filter. Monitor for cytokine release syndrome for at least 16 hours following first three infusions and then as clinically indicated
Prepared by	Puneet Kaur
Source	Tebentafusp-tebn (Kimmtrak) [prescribing information]. Conshohocken, PA: Immunocore Commercial LLC; January 2022.

Faricimab-svoa / Vabysmo / Genentech	
Generic Name / Brand Name / Company	Faricimab-svoa / Vabysmo / Genentech
Date of approval	1/28/22
Drug Class (Mechanism of Action if novel agent)	Vascular endothelial growth factor (VEGF) and angiopoietin-2 inhibitor
Indication	For the treatment of neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME)
Comparative agent – Therapeutic interchange?	Aflibercept, brolucizumab, pegaptanib, ranibizumab
Dosage forms/strengths.	Intravitreal injection: 120 mg/mL solution in a single-dose vial
Common Dose/sig	For nAMD: 6 mg (0.05 mL) administered via intravitreal injection every 4 weeks for 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to determine whether to administer a 6 mg dose per one of the following regimens: (1) weeks 28 and 44, (2) weeks 24, 36, and 48, (3) weeks 20, 28, 36, and 44. For DME: 6 mg (0.05 mL) administered via intravitreal injection either (1) every 4 weeks for 4 doses, followed by optical coherence tomography to determine the appropriate interval thereafter, or (2) every 4 weeks for 6 doses, followed by every 8 weeks for the next 28 weeks.
DEA Schedule	None
Date of market availability	Early 2022
Similar Medication Names	Fremanezumab
Clinical Use Evaluation	
Common Adverse Effects	≥2%: conjunctival hemorrhage, vitreous floaters; retinal pigment epithelial tear; intraocular pressure increased; eye pain; intraocular inflammation
Severe Adverse Effects	Endophthalmitis and retinal detachments, increased intraocular pressure, thromboembolic events
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Intraocular pressure
Used in Pediatric Areas	Safety and effectiveness not established
Renal or Hepatic Dosing	No adjustments required in renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Ocular or periocular infections Active intraocular inflammation Hypersensitivity to any product ingredients Warnings and precautions: Endophthalmitis and retinal detachment have been associated with intravitreal injections Transient increases in intraocular pressure have been observed with 60 minutes of intravitreal injection, including with faricimab-svoa Thromboembolic events are a potential risk of VEGF inhibitors, though a low rate was observed in clinical trials of faricimab-svoa
Special administration technique or considerations	Must be administered via intravitreal injection under sterile conditions. Sterile supplies for intraocular paracentesis should be available and ready if needed. If the contralateral eye requires treatment with faricimab-svoa, a new syringe should be prepared and the sterile field and all equipment should be changed prior to the second administration.
Prepared by	Regan Smith
Source	Vabysmo (faricimab-svoa) [prescribing information]. South San Francisco, CA: Genentech, Inc.; January 2022.

COVID-19 Vaccine, mRNA / Spikevax / Moderna	
Generic Name / Brand Name / Company	COVID-19 Vaccine, mRNA / Spikevax / Moderna
Date of approval	1/31/22
Drug Class (Mechanism of Action if novel agent)	Vaccines
Indication	Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults.
Comparative agent – Therapeutic interchange?	Comirnaty
Dosage forms/strengths.	Suspension for injection, in 5.5 mL and 7.5 mL multi-dose vials
Common Dose/sig	Two 0.5 mL IM doses administered 1 month apart
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	COVID-19 Vaccine, mRNA
Clinical Use Evaluation	
Common Adverse Effects	>10%: injection site pain, fatigue, headache, myalgia, chills, arthralgia, nausea/vomiting, axillary swelling/tenderness, fever, injection site swelling, injection site erythema
Severe Adverse Effects	Myocarditis and pericarditis, angioedema
Severe Drug-Drug Interactions	None
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	No dosage adjustments in renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: known history of severe allergic reaction to any component of the vaccine Warnings: Acute allergic reactions Myocarditis and pericarditis Syncope may occur Immunocompromised persons may have diminished response
Special administration technique or considerations	Moderna COVID-19 vaccine, mRNA remains available for expanded uses under the EUA
Prepared by	Terri Levien
Source	Spikevax (COVID-19 Vaccine, mRNA) [prescribing information]. Cambridge, MA: Moderna US, Inc.; January 2022.