Table 6g. Characteristics of Immunomodulators

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- The information in this table is derived from data on the use of these drugs for FDA-approved indications or in investigational trials, and it is supplemented with data on their use in patients with COVID-19, when available.
- For dose modifications for patients with organ failure or those who require extracorporeal devices, please refer to product labels or EUAs, when available.
- There are currently not enough data to determine whether certain medications can be safely coadministered with therapies for the treatment of COVID-19. When using concomitant medications with similar toxicity profiles, consider performing additional safety monitoring.
- The potential additive, antagonistic, or synergistic effects and the safety of using certain combination therapies for the treatment of COVID-19 are unknown. Clinicians are encouraged to report AEs to the FDA *Medwatch* program.
- For drug interaction information, please refer to product labels and visit the Liverpool COVID-19 Drug Interactions website.
- For the Panel's recommendations on using the drugs listed in this table, please refer to the drug-specific sections of the Guidelines, to Therapeutic Management of Nonhospitalized Adults With COVID-19, and Therapeutic Management of Hospitalized Adults With COVID-19.

Drug Name	Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Corticosteroid (Systemic) *Recommended by the Panel for the treatment of COVID-19 in certain hospitalized patients.*					
Dexamethasone (Systemic)	**Dose for COVID-19:** • DEX 6 mg IV or PO once daily for up to 10 days or until hospital discharge, whichever comes first[1]	• Hyperglycemia • Secondary infections • Reactivation of latent infections (e.g., HBV, HSV, strongyloidiasis, TB) • Cases of disseminated strongyloidiasis have been reported in patients with COVID-19 during treatment with corticosteroids and tocilizumab.	• Blood glucose • BP • Signs and symptoms of new infection	• Moderate CYP3A4 inducer • CYP3A4 substrate	• If DEX is not available, an alternative corticosteroid (e.g., prednisone, methylprednisolone, hydrocortisone) can be used. • The approximate total daily dose equivalencies for these glucocorticoids to DEX 6 mg (PO or IV) are: • Prednisone 40 mg • Methylprednisolone 32 mg • Hydrocortisone 160 mg • A list of clinical trials is available: Dexamethasone

Drug Name	Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Corticosteroid (Systemic), continued					
		• Psychiatric disturbances • Avascular necrosis • Adrenal insufficiency • Increased BP • Peripheral edema • Myopathy (particularly if used with NMBAs)			
Kinase Inhibitors					
Janus Kinase Inhibitors *Baricitinib and tofacitinib: Recommended by the Panel for the treatment of COVID-19 in certain hospitalized patients.* *Ruxolitinib: Not recommended by the Panel for the treatment of COVID-19. Currently under investigation in clinical trials.*					
Baricitinib[2]	**FDA-Approved Doses for COVID-19 for Adults Aged ≥18 Years**[2] *eGFR ≥60 mL/min/1.73 m²:* • Baricitinib 4 mg PO once daily *eGFR 30 to <60 mL/min/1.73 m²:* • Baricitinib 2 mg PO once daily *eGFR 15 to <30 mL/min/1.73 m²:* • Baricitinib 1 mg PO once daily *eGFR <15 mL/min/1.73 m²:* • **Not recommended**	• Lymphoma and other malignancies • Thrombosis • GI perforation • Treatment-related changes in lymphocytes, neutrophils, Hgb, liver enzymes • HSV reactivation • Herpes zoster • Serious cardiac-related events (e.g., MI, stroke)	• CBC with differential • Renal function • Liver enzymes • New infections	• Dose modification is recommended when administering concurrently with a strong OAT3 inhibitor.	• See the FDA label[2] and EUA[3] for dosing guidance for patients with: • ALC <200 cells/μL • ANC <500 cells/μL • If increases in ALT or AST are observed and DILI is suspected, interrupt baricitinib treatment until the diagnosis of DILI is excluded. • Baricitinib tablets can be taken orally or crushed, dispersed in water, and given via a gastrostomy tube.[2] • A list of clinical trials is available: Baricitinib **Availability:** • Baricitinib is approved by the FDA for the treatment of COVID-19 for adults aged ≥18 years and is

Drug Name	Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Kinase Inhibitors, continued					
Janus Kinase Inhibitors, *continued*					
	FDA EUA Dose for Children Aged 9–17 Years:[3] • Same as adults **FDA EUA Doses for Children Aged 2 to <9 Years**[3] *eGFR ≥60 mL/min/1.73m²:* • Baricitinib 2 mg PO once daily *eGFR 30 to <60 mL/min/1.73m²:* • Baricitinib 1 mg PO once daily *eGFR <30 mL/min/1.73m²:* • **Not recommended** **Duration of Therapy:** • Up to 14 days or until hospital discharge				available through an FDA EUA for children aged 2–17 years who require supplemental oxygen, NIV, MV, or ECMO.[3]
Ruxolitinib	**Dose for FDA-Approved Indications:** • Ruxolitinib 5 mg–20 mg PO twice daily **Dose for COVID-19 in Clinical Trials:** • Ruxolitinib 5 mg PO twice daily for 14 days[4]	• Thrombocytopenia • Anemia • Neutropenia • Liver enzyme elevations • Risk of infection • Dizziness • Headache • Diarrhea • CPK elevation • Herpes zoster	• CBC with differential • Liver enzymes • New infections	• Requires dose modification when administered with strong CYP3A4 inhibitor • Avoid use with fluconazole doses >200 mg.	• May require dose modification in patients with hepatic impairment, moderate or severe renal impairment, or thrombocytopenia • A list of clinical trials is available: Ruxolitinib

Drug Name	Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Kinase Inhibitors, continued					
Janus Kinase Inhibitors, *continued*					
Tofacitinib	**Dose for COVID-19 in Clinical Trials:** • Tofacitinib 10 mg PO twice daily for up to 14 days or until hospital discharge[5]	• Thrombotic events (e.g., PE, DVT, arterial thrombosis) • Anemia • Risk of infection • GI perforation • Diarrhea • Headache • Herpes zoster • Lipid elevations • Liver enzyme elevations • Lymphoma and other malignancies • Serious cardiac-related events (e.g., MI, stroke)	• CBC with differential • Liver enzymes • New infections	• Requires dose modification when administered with strong CYP3A4 inhibitors or when used with a moderate CYP3A4 inhibitor that is coadministered with a strong CYP2C19 inhibitor. • Coadministration with strong CYP3A4 inducers **is not recommended**.	• Avoid use in patients with ALC <500 cells/mm^3, ANC <1,000 cells/mm^3, or Hgb <9 grams/dL. • May require dose modification in patients with moderate or severe renal impairment or moderate hepatic impairment. • A list of clinical trials is available: Tofacitinib
Interleukin-6 Inhibitors					
Anti-Interleukin-6 Receptor Monoclonal Antibodies *Recommended by the Panel for the treatment of COVID-19 in certain hospitalized patients.*					
Sarilumab[6]	**Dose for COVID-19 in Clinical Trials:** • Single dose of sarilumab 400 mg IV[7]	• Neutropenia, thrombocytopenia • GI perforation • HSR • Increased liver enzymes • HBV reactivation • Infusion-related reaction	• HSR • Infusion reactions • Neutrophils • PLT • Liver enzymes	• Elevated IL-6 may downregulate CYP enzymes; thus, use of sarilumab may lead to increased metabolism of drugs that are CYP substrates. • The effects of sarilumab on CYP enzymes may persist for weeks after the drug is stopped.	• Sarilumab **is not recommended** in patients with ALT or AST >1.5 times the upper limit of the reference range, ANC <2,000 cells/mm^3, or PLT <150,000 cells/mm^3.[6] • Treatment with sarilumab may mask signs of acute inflammation or infection by suppressing fever and CRP levels.

Drug Name	Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Interleukin-6 Inhibitors, continued					
Anti-Interleukin-6 Receptor Monoclonal Antibodies, *continued*					
					• A list of clinical trials is available: Sarilumab **Availability:** • The IV formulation of sarilumab is not approved by the FDA, but in a clinical trial, a single SUBQ dose (using the prefilled syringe, **not** the prefilled pen) of sarilumab 400 mg was reconstituted in 100 cc 0.9% NaCl and given as an IV infusion over 1 hour. • Sarilumab infusion should be used within 4 hours of preparation; it can be stored at room temperature until administered.
Tocilizumab[8]	**FDA EUA Doses for COVID-19 in Hospitalized Patients Aged ≥2 Years** *Body Weight ≥30 kg:* • Tocilizumab 8 mg/kg (maximum 800 mg) by IV infusion over 1 hour • Per the EUA, if clinical signs or symptoms worsen or do not improve following the first infusion, 1 additional dose may be administered ≥8 hours after the first dose.	• Infusion-related reaction • HSR • GI perforation • Hepatotoxicity • Treatment-related changes on laboratory tests for neutrophils, PLT, lipids, and liver enzymes • HBV reactivation • Secondary infections	• HSR • Infusion reactions • Neutrophils • PLT • Liver enzymes	• Inhibition of IL-6 may lead to increased metabolism of coadministered drugs that are CYP450 substrates. • The effects of tocilizumab on CYP enzymes may persist for weeks after the drug is stopped.	• Tocilizumab **is not recommended** in patients with ALT or AST >10 times the upper limit of the reference range, ANC <1,000 cells/mm^3, or PLT <50,000 cells/mm^3.[9] • The SUBQ formulation of tocilizumab **is not intended** for IV administration. • A list of clinical trials is available: Tocilizumab **Availability:** • IV tocilizumab, which has been approved for non-

Drug Name	Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Interleukin-6 Inhibitors, continued					
Anti-Interleukin-6 Receptor Monoclonal Antibodies, *continued*					
	Body Weight <30 kg: • Tocilizumab 12 mg/kg by IV infusion over 1 hour • Per the EUA, if clinical signs or symptoms worsen or do not improve following the first infusion, 1 additional dose may be administered ≥8 hours after the first dose.	• Cases of disseminated strongyloidiasis have been reported in patients with COVID-19 during treatment with tocilizumab and corticosteroids.			COVID-19 indications, is available commercially and through an FDA EUA for the treatment of COVID-19 in hospitalized adults and pediatric patients aged ≥2 years who are receiving systemic corticosteroids and require supplemental oxygen, NIV, MV, or ECMO. The EUA does not authorize the use of SUBQ administration of tocilizumab for the treatment of COVID-19.[9]
Anti-Interleukin-6 Monoclonal Antibody *Not recommended by the Panel for the treatment of COVID-19. Currently under investigation in clinical trials.*					
Siltuximab	**FDA-Approved Dose for Multicentric Castleman Disease:** • Siltuximab 11 mg/kg by IV infusion over 1 hour every 3 weeks[10] **Dose for COVID-19:** • Dose and duration unknown	• Infusion-related reaction • HSR • GI perforation • Neutropenia • HTN • Dizziness • Rash • Pruritus • Hyperuricemia	• Neutrophils • HSR • Infusion reactions	• Elevated IL-6 may downregulate CYP enzymes; use of siltuximab may lead to increased metabolism of drugs that are CYP substrates. • The effects of siltuximab on CYP enzymes may persist for weeks after therapy is stopped.	• Siltuximab **is not recommended** in patients with ANC <1,000 cells/mm^3, Hgb >17 g/dL, or PLT <75,000 cells/mm^3.[10] • Treatment with siltuximab may mask signs of acute inflammation or infection by suppressing fever and CRP levels. • A list of clinical trials is available: Siltuximab

Drug Name	Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Colchicine *Not recommended by the Panel for the treatment of COVID-19. Currently under investigation in clinical trials.*					
Colchicine	**Dose for COVID-19 in COLCORONA Trial:** • Colchicine 0.5 mg twice daily for 3 days, then once daily for 27 days[11] **Dose for COVID-19 in COLCOVID Trial:** • Colchicine 1.5 mg PO followed by 0.5 mg PO within 2 hours of initial dose, then twice daily for 14 days or until hospital discharge, whichever comes first[12]	• Diarrhea • Nausea • Vomiting • Cramping • Abdominal pain • Bloating • Loss of appetite • Neuromyotoxicity (rare)[13] • Blood dyscrasias (rare)	• CBC • Renal function • Hepatic function	• P-gp and CYP3A4 substrate • The risk of myopathy may be increased with the concomitant use of certain HMG-CoA reductase inhibitors (e.g., atorvastatin, lovastatin, simvastatin) due to potential competitive interactions mediated by P-gp and CYP3A4 pathways. • Fatal colchicine toxicity has been reported in individuals with renal or hepatic impairment who used colchicine in conjunction with P-gp inhibitors or strong CYP3A4 inhibitors.	• Use of colchicine should be avoided in patients with severe renal insufficiency. Patients with moderate renal insufficiency who receive the drug should be monitored for AEs. • A list of clinical trials is available: Colchicine **Availability:** • In the COLCORONA and COLCOVID trials, 0.5 mg colchicine tablets were used for dosing; in the United States, colchicine is available as 0.6 mg tablets.
Corticosteroids (Inhaled) *Not recommended by the Panel for the treatment of COVID-19. Currently under investigation in clinical trials.*					
Budesonide (Inhaled)	**Dose for COVID-19 in Clinical Trials:** • Budesonide 800 mcg oral inhalation twice daily until symptom resolution or for up to 14 days[14,15]	• Secondary infections • Oral thrush • Systemic AEs (less common)	• Signs of AEs involving the oral mucosa or throat, including thrush • Signs of systemic corticosteroid effects (e.g., adrenal suppression)	• CYP3A4 substrate • **Do not use** with strong CYP3A4 inhibitors.	• A list of clinical trials is available: Inhaled Budesonide

Drug Name	Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Corticosteroids (Inhaled), continued					
Ciclesonide (Inhaled)	**Dose for COVID-19 in Clinical Trials:** • Ciclesonide 160 mcg as 2 MDI inhalations twice daily for 30 days[16]	• Secondary infections • Oral thrush • Systemic AEs (less common)	• Signs of AEs involving the oral mucosa or throat, including thrush • Signs of systemic corticosteroid effects (e.g., adrenal suppression)	• CYP3A4 substrate • Strong CYP3A4 inhibitors are expected to have less of an effect on ciclesonide exposure than they have on budesonide exposure.	• A list of clinical trials is available: Ciclesonide
Fluvoxamine *Not recommended by the Panel for the treatment of COVID-19. Currently under investigation in clinical trials.*					
Fluvoxamine	**Doses for COVID-19 in Clinical Trials:** • Fluvoxamine 50 mg twice daily • Fluvoxamine 100 mg twice daily • Fluvoxamine 100 mg 3 times daily	• Nausea • Diarrhea • Dyspepsia • Asthenia • Insomnia • Somnolence • Sweating • Suicidal ideation (rare)	• Hepatic function • Drug interactions • Withdrawal symptoms during dose tapering	• CYP2D6 substrate • Fluvoxamine inhibits several CYP isoenzymes (CYP1A2, CYP2C9, CYP3A4, CYP2C19, CYP2D6) • Coadministration of tizanidine, thioridazine, alosetron, or pimozide with fluvoxamine is **contraindicated**.	• Fluvoxamine may enhance anticoagulant effects of antiplatelets and anticoagulants; consider additional monitoring when these drugs are used concomitantly with fluvoxamine. • The use of MAOIs concomitantly with fluvoxamine or within 14 days of treatment with fluvoxamine is **contraindicated**. • A list of clinical trials is available: Fluvoxamine

Drug Name	Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Interleukin-1 Inhibitors *Not recommended by the Panel for the treatment of COVID-19. Currently under investigation in clinical trials.*					
Anakinra	**FDA-Approved Dose for Rheumatoid Arthritis:** • Anakinra 100 mg SUBQ once daily **Doses for COVID-19 in Clinical Trials:** • Dose and duration vary by study. • Has also been used as IV infusion.	• Neutropenia (particularly when used concomitantly with other agents that can cause neutropenia) • Anaphylaxis and angioedema • Headache • Nausea • Diarrhea • Sinusitis • Arthralgia • Flu-like symptoms • Abdominal pain • Injection site reactions • Liver enzyme elevations	• CBC with differential • Liver enzymes • Renal function; reduce dose if CrCl <30 mL/min.	• Use with TNF-blocking agents **is not recommended** due to increased risk of infection.	• Anakinra for IV administration is not an approved formulation in the United States.[17] • A list of clinical trials is available: Anakinra
Canakinumab	**FDA-Approved Dose for Systemic JIA:** • Canakinumab 4 mg/kg (maximum 300 mg) SUBQ every 4 weeks[18]	• HSR • Neutropenia • Nasopharyngitis • Diarrhea • Respiratory tract infections • Bronchitis • Gastroenteritis • Pharyngitis • Musculoskeletal pain • Vertigo • Abdominal pain • Injection site reactions • Liver enzyme elevations	• HSR • CBC with differential • Liver enzymes	• Binding of canakinumab to IL-1 may increase formation of CYP enzymes and alter metabolism of drugs that are CYP substrates. • Use with TNF-blocking agents **is not recommended** due to potential increased risk of infection.	• Canakinumab for IV administration is not an approved formulation in the United States.[18] • A list of clinical trials is available: Canakinumab

Drug Name	Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Non-SARS-CoV-2 Specific Immunoglobulin *Primarily used for the treatment of multisystem inflammatory syndrome in children (MIS-C). Currently under investigation in clinical trials.*					
Non-SARS-CoV-2 Specific Immunoglobulin	• Dose varies based on indication and formulation.	• Allergic reactions, including anaphylaxis • Renal failure • Thrombotic events • Aseptic meningitis syndrome • Hemolysis • TRALI • Transmission of infectious pathogens • AEs may vary by formulation. • AEs may be increased with high dose or rapid infusion or in patients with underlying conditions.	• Transfusion-related reactions • Vital signs at baseline and during and after infusion • Renal function; discontinue treatment if function deteriorates.	• Not a substrate of CYP	• A list of clinical trials is available: Intravenous Immunoglobulin

Key: AE = adverse event; ALC = absolute lymphocyte count; ALT = alanine transaminase; ANC = absolute neutrophil count; AST = aspartate aminotransferase; BP = blood pressure; CBC = complete blood count; CPK = creatine phosphokinase; CrCl = creatinine clearance; CRP = C-reactive protein; CYP = cytochrome P450; DEX = dexamethasone; DILI = drug-induced liver injury; DVT = deep vein thrombosis; ECMO = extracorporeal membrane oxygenation; eGFR = estimated glomerular filtration rate; EUA = Emergency Use Authorization; FDA = Food and Drug Administration; GI = gastrointestinal; HBV = hepatitis B virus; Hgb = hemoglobin; HSR = hypersensitivity reaction; HSV = herpes simplex virus; HTN = hypertension; IL = interleukin; IV = intravenous; JIA = juvenile idiopathic arthritis; MAOI = monoamine oxidase inhibitor; MDI = metered dose inhaler; MI= myocardial infarction; MV = mechanical ventilation; NaCl = sodium chloride; NIV = noninvasive ventilation; NMBA = neuromuscular blocking agents; OAT = organic anion transporter; the Panel = the COVID-19 Treatment Guidelines Panel; PE = pulmonary embolism; P-gp= P-glycoprotein; PLT = platelet count; PO = orally; SUBQ = subcutaneous; TB = tuberculosis; TNF = tumor necrosis factor; TRALI = transfusion-related acute lung injury

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