discontinue breastfeeding or discontinue the drug, taking into account the importance of the drug to the mother.

Drug Interactions

Metabolism/Transport Effects None known.

Avoid Concomitant Use

Avoid concomitant use of Basiliximab with any of the following: Abrocitinib; Baricitinib; BCG Products; Brivudine; Cladribine; Dengue Tetravalent Vaccine (Live); Deucravacitinib; Filgotinib; Mumps- Rubella- or Varicella-Containing Live Vaccines; Nadofaragene Firadenovec; Natalizumab; Pimecrolimus; Poliovirus Vaccine (Live/Trivalent/Oral); Ruxolitinib (Topical); Tacrolimus (Topical); Talimogene Laherparepvec; Tertomotide; Tofacitinib; Typhoid Vaccine; Upadacitinib; Vaccines (Live); Yellow Fever Vaccine

Increased Effect/Toxicity

Basiliximab may increase the levels/effects of: Antithymocyte Globulin (Equine); Baricitinib; BCG Products; Cladribine; Dengue Tetravalent Vaccine (Live); Denosumab; Inebilizumab; Leflunomide; Mumps- Rubella- or Varicella-Containing Live Vaccines; Nadofaragene Firadenovec; Natalizumab; Ocrelizumab; Ofatumumab; Pimecrolimus; Poliovirus Vaccine (Live/Trivalent/Oral); Polymethylmethacrylate; Ruxolitinib (Topical); Tacrolimus (Topical); Talimogene Laherparepvec; Tofacitinib; Typhoid Vaccine; Ublituximab; Upadacitinib; Yellow Fever Vaccine

The levels/effects of Basiliximab may be increased by: Abrocitinib; Brivudine; Deucravacitinib; Filgotinib; Sphingosine 1-Phosphate (S1P) Receptor Modulator; Vaccines (Live)

Decreased Effect

Basiliximab may decrease the levels/effects of: Antidiabetic Agents; BCG Products; Brincidofovir; Coccidioides immitis Skin Test; COVID-19 Vaccine (Adenovirus Vector); COVID-19 Vaccine (Inactivated Virus); COVID-19 Vaccine (mRNA); COVID-19 Vaccine (Subunit); COVID-19 Vaccine (Virus-like Particles); Dengue Tetravalent Vaccine (Live); Influenza Virus Vaccines; Mumps-Rubella- or Varicella-Containing Live Vaccines; Pidotimod; Pneumococcal Vaccines; Poliovirus Vaccine (Live/Trivalent/Oral); Rabies Vaccine; Sipuleucel-T; Tertomotide; Typhoid Vaccine; Vaccines (Inactivated/Non-Replicating); Yellow Fever Vaccine

The levels/effects of Basiliximab may be decreased by: Efgartigimod Alfa; Vaccines (Live)

Monitoring Parameters Monitor for signs and symptoms of acute rejection; hypersensitivity, infection

Dosage Forms: US Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Solution Reconstituted, Intravenous [preservative free]: Simulect: 10 mg (1 ea); 20 mg (1 ea)

Dosage Forms: Canada Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Solution Reconstituted, Intravenous: Simulect: 20 mg (1 ea)

Mechanism of Action Basiliximab is a chimeric (murine/human) immunosuppressant monoclonal antibody which blocks the alpha-chain of the interleukin-2 (IL-2) receptor complex; this receptor is expressed on activated T lymphocytes and is a critical pathway for activating cell-mediated allograft rejection

Pharmacokinetics (Adult Data Unless Noted)

Duration: Mean: 36 days ± 14 days (determined by IL-2R alpha saturation in patients also on cyclosporine and corticosteroids).

Distribution: Mean: V_d: Children 1 to 11 years: 4.8 ± 2.1 L; Adolescents 12 to 16 years: 7.8 ± 5.1 L; Adults: 8.6 ± 4.1 L.

Half-life elimination: Children 1 to 11 years: 9.5 ± 4.5 days; Adolescents 12 to 16 years: 9.1 ± 3.9 days; Adults: Mean: 7.2 ± 3.2 days.

Excretion: Clearance:

Children 1 to 11 years: 17 ± 6 mL/hour; in pediatric liver transplant recipients, significant basiliximab loss through ascites fluid can increase total body clearance and reduce IL-2R (CD25) saturation duration; dosage adjustments may be necessary (Cintorino 2006; Kovarik 2002; Spada 2006).

Adolescents 12 to 16 years: 31 ±19 mL/hour.

Adults: 41 ± 19 mL/hour.

- **Baxdela** *see* Delafloxacin *on page 611*
- **BAY 59-7939** *see* Rivaroxaban *on page 2017*
- **BAY 63-2521** *see* Riociguat *on page 1995*
- **Bayer Aspirin [OTC]** *see* Aspirin *on page 167*
- **Bayer Aspirin EC Low Dose [OTC]** *see* Aspirin *on page 167*
- **Bayer Aspirin Extra Strength [OTC]** *see* Aspirin *on page 167*
- **Bayer Aspirin Regimen Adult Low Strength [OTC]** *see* Aspirin *on page 167*
- **Bayer Aspirin Regimen Children's [OTC]** *see* Aspirin *on page 167*
- **Bayer Aspirin Regimen Regular Strength [OTC]** *see* Aspirin *on page 167*
- **Bayer Genuine Aspirin [OTC]** *see* Aspirin *on page 167*
- **Bayer Plus Extra Strength [OTC]** *see* Aspirin *on page 167*
- **Bayer Women's Low Dose Aspirin [OTC]** *see* Aspirin *on page 167*
- **Baza Antifungal [OTC]** *see* Miconazole (Topical) *on page 1513*
- **Bazedoxifene and Estrogens (Conjugated/Equine)** *see* Estrogens (Conjugated/Equine) and Bazedoxifene *on page 842*
- **Bazedoxifene and Oestrogens** *see* Estrogens (Conjugated/Equine) and Bazedoxifene *on page 842*
- **BC-3781** *see* Lefamulin *on page 1303*
- **BCL-2 Inhibitor GDC-0199** *see* Venetoclax *on page 2375*
- **BCX-1812** *see* Peramivir *on page 1792*
- **BCX7353** *see* Berotralstat *on page 240*

Bebtelovimab

Pharmacologic Category Antiviral Agent; Monoclonal Antibody

Dosing

Adult

COVID-19, outpatients with high risk of progression to severe illness (alternative agent) (off-label use):

Note: Use is not authorized for patients who are hospitalized or require new or increased oxygen therapy due to COVID-19; outcomes may be worse if used in patients requiring high-flow oxygen or mechanical ventilation (FDA 2022).

IV: 175 mg as a single dose; initiate as soon as possible after COVID-19 diagnosis and within 7 days of symptom onset. **Note:** Consider local prevalence of SARS-CoV-2 variants when evaluating treatment options (FDA 2022, NIH 2022). Further information may be found at: https://covid.cdc.gov/covid-data-tracker/#variant-proportions.

Older Adult Refer to adult dosing (FDA 2022).

Altered Kidney Function: Adult No dosage adjustment recommended (FDA 2022).

Hepatic Impairment: Adult

Mild impairment: No dosage adjustment recommended (FDA 2022).

Moderate to severe impairment: There are no dosage adjustments provided (has not been studied) (FDA 2022).

Administration: Adult

Note: Infuse in an environment equipped to monitor for and manage hypersensitivity and infusion-related reactions (eg, fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia, chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness, diaphoresis); if severe or life-threatening hypersensitivity reactions, including anaphylaxis, occur, immediately discontinue infusion and provide emergency care (FDA 2022).

IV: Remove vial from refrigerator and allow to come to room temperature for ~20 minutes; do not expose to direct heat; do not shake. The solution should be clear to opalescent and colorless to slightly yellow or slightly brown; discard if solution is cloudy, discolored, or contains particulate matter. Withdraw dose using a disposable polypropylene syringe; discard any product remaining in vial. Administer dose immediately after withdrawing if possible; if dose is refrigerated, allow syringe to come to room temperature prior to administration (~20 minutes). If used, attach and prime IV extension set made of polyethylene or PVC with or without diethylhexylphthalate (**Note:** Prior to March 2022, use of an IV extension set was required; however, as of March 2022 the use of an IV extension set is now optional). Administer IV over ≥30 seconds; following administration, flush the injection line with NS to ensure delivery of entire dose (FDA 2022).

Storage/Stability
Refrigerate intact vials at 2°C to 8°C (36°F to 46°F); protect from light. Do not freeze or shake (FDA 2022).
Prepared syringe should be administered as soon as possible. If immediate administration is not possible, store syringe for up to 24 hours refrigerated at 2°C to 8°C (36°F to 46°F) or up to 7 hours at room temperature (20°C to 25°C [68°F to 77°F]); discard any unused portion (FDA 2022).

Adverse Reactions Bebtelovimab is currently under investigation for use in the treatment of COVID-19. Serious or unexpected adverse reactions not previously reported may occur; refer to emergency use authorization (EUA) for information regarding reporting serious adverse reactions (FDA 2022). Adverse reactions reported for monotherapy and combination therapy with etesevimab in adolescents and adults for the authorized dose and unauthorized higher dose.
<1%:
Dermatologic: Pruritus, skin rash
Gastrointestinal: Nausea, vomiting
Miscellaneous: Infusion related reaction

Contraindications There are no contraindications listed in the emergency use authorization.

Warnings/Precautions Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of other SARS-CoV-2 human immunoglobulin G1 (IgG1) monoclonal antibodies and could occur with administration of bebtelovimab. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive care. Infusion-related reactions (eg, fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia [eg, atrial fibrillation, sinus tachycardia, bradycardia], chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash, including urticaria, pruritus, myalgia, vasovagal reactions [eg, presyncope, syncope], dizziness, diaphoresis) have been observed with administration of bebtelovimab and up to 24 hours after the infusion. Monitor patients after administration for ≥1 hour; if an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care (FDA 2022). Some dosage forms may contain polysorbate 80 (also known as Tweens). Hypersensitivity reactions, usually a delayed reaction, have been reported following exposure to pharmaceutical products containing polysorbate 80 in certain individuals (Isaksson 2002; Lucente 2000; Shelley 1995). Thrombocytopenia, ascites, pulmonary deterioration, and renal and hepatic failure have been reported in premature neonates after receiving parenteral products containing polysorbate 80 (Alade 1986; CDC 1984). See fact sheet for health care providers.

Development of SARS-CoV-2 variants with reduced susceptibility to bebtelovimab may potentially increase risk of treatment failure; consider local prevalence of SARS-CoV-2 variants, if available, when evaluating treatment options (FDA 2022; NIH 2022). Clinical worsening of COVID-19, including signs or symptoms of fever, hypoxia or increased respiratory difficulty, arrhythmia (eg, atrial fibrillation, bradycardia, tachycardia), fatigue, and altered mental status, has been reported after administration of SARS-CoV-2 monoclonal antibodies; some of these events required hospitalization. It is not known if these events were related to SARS-CoV-2 monoclonal antibody use or were due to COVID-19 progression (FDA 2022). Bebtelovimab has not been studied in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bebtelovimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high-flow oxygen or mechanical ventilation. Bebtelovimab is not authorized for use in patients who are hospitalized due to COVID-19, require oxygen therapy and/or respiratory support due to COVID-19, or require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non–COVID-19 related comorbidity (FDA 2022).

Reproductive Considerations Reproductive toxicity studies have not been conducted (FDA 2022).

Pregnancy Considerations
Bebtelovimab is under FDA emergency use authorization (EUA) for the treatment of COVID-19. Reproductive toxicity studies have not been conducted (FDA 2022).

Bebtelovimab is a humanized monoclonal antibody (IgG_1). Human IgG crosses the placenta. Exposure is dependent upon the IgG subclass, maternal serum concentrations, placental integrity, newborn birth weight, and GA, generally increasing as pregnancy progresses. The lowest exposure would be expected during the period of organogenesis and the highest during the third trimester (Clements 2020; Palmeira 2012; Pentsuk 2009). The potential benefits or risks of in utero exposure of bebtelovimab to the fetus are not known (FDA 2022).

The risk of severe illness from COVID-19 infection is increased in symptomatic pregnant patients compared to nonpregnant patients. Pregnant and recently pregnant patients with moderate or severe infection are at increased risk of complications such as hypertensive disorders of pregnancy, postpartum hemorrhage, or other infections compared to pregnant patients without COVID-19. Symptomatic pregnant patients may require ICU admission, mechanical ventilation, or ventilatory support (ECMO) compared to symptomatic nonpregnant patients. Other adverse pregnancy outcomes include preterm birth and stillbirth. The risk of coagulopathy, cesarean delivery, and maternal death may be increased; neonates have an increased risk for NICU admission. Maternal age and comorbidities such as diabetes, hypertension, lung disease, and obesity may also increase the risk of severe illness in pregnant and recently pregnant patients (ACOG 2023; NIH 2022).

In general, the treatment of COVID-19 infection during pregnancy is the same as in nonpregnant patients. However, because data for most therapeutic agents in pregnant patients are limited, treatment options should be evaluated as part of a shared decision-making process (NIH 2022). Use may be considered in nonhospitalized, COVID-19–positive, pregnant patients who have mild to moderate symptoms, especially patients with 1 or more additional risk factors (eg, BMI >25, cardiovascular disease, chronic kidney disease, diabetes mellitus) (ACOG 2023). According to the EUA, dose adjustments are not recommended for patients who are pregnant (FDA 2022). Information related to the treatment of COVID-19 during pregnancy continues to emerge; refer to current guidelines for the treatment of pregnant patients.

Data collection to monitor maternal and infant outcomes following exposure to COVID-19 during pregnancy is ongoing. Health care providers are encouraged to enroll patients exposed to COVID-19 during pregnancy in the Organization of Teratology Information Specialists pregnancy registry (1-877-311-8972; https://mothertobaby.org/join-study/).

Breastfeeding Considerations
It is not known if bebtelovimab is present in breast milk.
Bebtelovimab is a humanized monoclonal antibody (IgG_1). Human IgG is present in breast milk; concentrations are dependent upon IgG subclass and postpartum age (Anderson 2021).
Bebtelovimab is under FDA emergency use authorization (EUA) for the treatment of COVID-19. Dose adjustments are not recommended for lactating patients. According to the EUA, the decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and the benefits of treatment to the mother (FDA 2022).
Lactating patients with ≥1 risk factor for severe illness from COVID-19 infection may be treated with monoclonal antibodies. Breast milk has not been found to be a source of COVID-19 infection and maternal infection is not a contraindication to breastfeeding. However, lactating patients with COVID-19 infection can transmit the virus through respiratory droplets and all precautions should be taken to avoid spreading the virus to the infant (eg, hand hygiene, mask wearing); alternatively, breast milk can be expressed and fed to the infant by someone without confirmed or suspected COVID-19 (ACOG 2023).
Interim guidance is available from the CDC for the care of lactating patients who are diagnosed with COVID-19 (https://www.cdc.gov/coronavirus/2019-ncov/hcp/care-for-breastfeeding-women.html). Information related to COVID-19 and breastfeeding is also available from the World Health Organization (https://www.who.int/news/item/28-04-2020-new-faqs-address-healthcare-workers-questions-on-breastfeeding-and-covid-19).

Drug Interactions
Metabolism/Transport Effects None known.
Avoid Concomitant Use There are no known interactions where it is recommended to avoid concomitant use.
Increased Effect/Toxicity There are no known significant interactions involving an increase in effect.
Decreased Effect There are no known significant interactions involving a decrease in effect.

Monitoring Parameters Monitor for ≥1 hour after injection for infusion-related reactions (FDA 2022).