Contributor Disclosures

For additional information see "Guselkumab: Patient drug information"

For abbreviations, symbols, and age group definitions show table

Brand Names: US

Tremfya; Tremfya Crohns Induction; Tremfya Pen

Brand Names: Canada

Tremfya

Pharmacologic Category

Antipsoriatic Agent; Interleukin-23 Inhibitor; Monoclonal Antibody

Dosing: Adult

Dosage guidance:

Safety: Prior to initiation, certain assessments (clinical and laboratory) are **required** with documentation and age-appropriate vaccinations should be up to date. In general, live vaccines should not be administered within 4 weeks prior to starting therapy (Ref). Refer to institutional protocols for vaccination and monitoring requirements prior to initiating therapy.

Crohn disease, moderate to severe

Crohn disease, moderate to severe:

Induction:

IV induction regimen: **IV:** 200 mg on weeks 0, 4, and 8.

OR

SUBQ induction regimen: **SUBQ:** 400 mg (as 2 consecutive 200 mg injections) on weeks 0, 4, and 8.

Maintenance: **SUBQ:** 100 mg every 8 weeks beginning at week 16 **or** 200 mg every 4 weeks beginning at week 12. **Note:** Use lowest effective dosage to maintain therapeutic response.

Plaque psoriasis

Plaque psoriasis: SUBQ: 100 mg at weeks 0, 4, and then every 8 weeks thereafter.

Psoriatic arthritis

Psoriatic arthritis: SUBQ: 100 mg at weeks 0, 4, and then every 8 weeks thereafter; may administer alone or in combination with conventional disease-modifying antirheumatic drugs (eg, methotrexate).

Ulcerative colitis, moderate to severe

Ulcerative colitis, moderate to severe:

Induction: **IV:** 200 mg on weeks 0, 4, and 8.

Maintenance: **SUBQ:** 100 mg every 8 weeks beginning at week 16 **or** 200 mg every 4 weeks beginning at week 12. **Note:** Use lowest effective dosage to maintain therapeutic response.

Dosing: Kidney Impairment: Adult

There are no dosage adjustments provided in the manufacturer's labeling (has not been studied).

Dosing: Liver Impairment: Adult

There are no dosage adjustments provided in the manufacturer's labeling (has not been studied).

Guselkumab-induced liver injury: Interrupt therapy if suspected until diagnosis excluded.

Dosing: Older Adult

Refer to adult dosing.

Adverse Reactions

The following adverse drug reactions and incidences are derived from product labeling unless otherwise specified. Adverse reactions reported in adults.

>10%:

Gastrointestinal: Abdominal pain (12% to 14%)

Immunologic: Antibody development (2% to 11%; neutralizing antibodies: 5% to 16%)

Infection: Infection (23%)

Respiratory: Respiratory tract infection (7% to 38%; including bronchitis, influenza, nasopharyngitis, pharyngitis, pneumonia, tonsillitis, upper respiratory tract infection, viral respiratory tract infection)

1% to 10%:

Dermatologic: Tinea (1%)

Gastrointestinal: Diarrhea (2% to 5%), gastroenteritis (1% to 4%)

Hepatic: Increased liver enzymes (3%)

Infection: Herpes simplex infection (1%)

Local: Injection-site reaction (4% to 9%)

Nervous system: Fatigue (3% to 4%), headache (3% to 8%)

Neuromuscular & skeletal: Arthralgia (3% to 8%)

<1%:

Dermatologic: Urticaria

Hematologic & oncologic: Decreased neutrophils

Infection: Candidiasis

Nervous system: Migraine

Respiratory: Tuberculosis disease

Postmarketing:

Dermatologic: Bullous pemphigoid (Burlando 2022), dermatitis (nummular) (Truong 2019), skin rash

Hypersensitivity: Hypersensitivity reaction (including anaphylaxis, severe hypersensitivity reaction)

Contraindications

Serious hypersensitivity to guselkumab or any component of the formulation.

Warnings/Precautions

Concerns related to adverse effects:

• Antibody formation: Formation of neutralizing anti-drug antibodies may occur but has not been associated with loss of efficacy for guselkumab (AAD/NPF [Menter 2019]).

• Hepatotoxicity: Drug-induced liver injury (AST 11 × ULN, ALT 18 × ULN, and total bilirubin 2.4 × ULN) occurred in a Crohn disease clinical trial patient receiving 3 doses of a higher than recommended induction dose; LFTs returned to normal following discontinuation of therapy, corticosteroid administration, and hospitalization. Consider other treatment options in patients with acute liver disease or cirrhosis.

• Hypersensitivity reactions: Serious hypersensitivity reactions, including anaphylaxis, may occur; may require hospitalization. Discontinue use and initiate appropriate therapy if serious hypersensitivity reactions occur.

• Infections: Guselkumab may increase the risk of infections; upper respiratory tract infections, gastroenteritis, tinea infections, and herpes simplex infections have occurred more frequently. Consider the risks versus benefits prior to treatment initiation in patients with a history of chronic or recurrent infection; treatment should not be initiated in patients with clinically important active infections until it is resolved or treated. Monitor for infections;

patients should seek medical attention for signs/symptoms of a clinically important infection (acute or chronic). If a serious infection develops or is unresponsive to appropriate therapy for the infection, monitor closely and discontinue guselkumab until the infection resolves.

• Tuberculosis: Patients should be evaluated for tuberculosis (TB) infection (latent TB) prior to initiating therapy. Do not administer to patients with TB disease (active TB). Treatment for TB infection should be administered prior to administering guselkumab. Consider anti-TB therapy prior to treatment initiation in patients with a history of TB infection or disease in whom an adequate course of TB treatment cannot be confirmed. Monitor closely for signs/symptoms of TB disease during and after guselkumab treatment.

Special populations:

• Patients with rheumatic musculoskeletal disease undergoing hip or knee replacement surgery: Hold biologic disease-modifying antirheumatic drugs (DMARDs) prior to surgery and plan surgery after the next dose is due. Surgery can occur after holding medication for 1 full dosing cycle (eg, for medications administered every 4 weeks, schedule surgery 5 weeks from last administered dose); therapy can be restarted once surgical wound shows evidence of healing (eg, no swelling, erythema, or drainage), sutures/staples are removed, and no ongoing nonsurgical site infections (typically ~14 days to reduce infection risk). Decisions to withhold therapy should be based on shared decision making; ensure the patient and their provider weigh risks of interrupting therapy and disease control versus risks of continuing therapy and surgical complications (ACR/AAHKS [Goodman 2022]).

Other warnings/precautions:

• Immunizations: Patients should be brought up to date with all immunizations before initiating therapy. Live vaccines should not be given concurrently; there are no data available concerning secondary transmission of infection by live vaccines in patients receiving therapy.

Dosage Forms: US

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

Solution, Intravenous [preservative free]:

Tremfya: 200 mg/20 mL (20 mL) [contains edetate (edta) disodium dihydrate, polysorbate 80]

Solution Auto-injector, Subcutaneous [preservative free]:

Tremfya: 100 mg/mL (1 mL); 200 mg/2 mL (2 mL) [contains polysorbate 80]

Tremfya Crohns Induction: 200 mg/2 mL (2 mL) [contains polysorbate 80]

Tremfya Pen: 100 mg/mL (1 mL) [contains polysorbate 80]

Solution Prefilled Syringe, Subcutaneous [preservative free]:

Tremfya: 100 mg/mL (1 mL); 200 mg/2 mL (2 mL) [contains polysorbate 80]

Generic Equivalent Available: US

No

Pricing: US

Solution (Tremfya Intravenous)

200 mg/20 mL (per mL): $873.99

Solution Auto-injector (Tremfya Crohns Induction Subcutaneous)

200 mg/2 mL (per mL): $8,739.87

Solution Auto-injector (Tremfya Pen Subcutaneous)

100 mg/mL (per mL): $17,479.73

Solution Auto-injector (Tremfya Subcutaneous)

100 mg/mL (per mL): $17,479.73

200 mg/2 mL (per mL): $8,739.87

Solution Prefilled Syringe (Tremfya Subcutaneous)

100 mg/mL (per mL): $17,479.73

200 mg/2 mL (per mL): $8,739.87

Disclaimer: A representative AWP (Average Wholesale Price) price or price range is provided as reference price only. A range is provided when more than one manufacturer's AWP price is available and uses the low and high price reported by the manufacturers to determine the range. The pricing data should be used for benchmarking purposes only, and as such should not be used alone to set or adjudicate any prices for reimbursement or purchasing functions or considered to be an exact price for a single product and/or manufacturer. Medi-Span expressly disclaims all warranties of any kind or nature, whether express or implied, and assumes no liability with respect to accuracy of price or price range data published in its solutions. In no event shall Medi-Span be liable for special, indirect, incidental, or consequential damages arising from use of price or price range data. Pricing data is updated monthly.

Dosage Forms: Canada

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

Solution Auto-injector, Subcutaneous:

Tremfya: 100 mg/mL (1 mL) [contains polysorbate 80]

Solution Prefilled Syringe, Subcutaneous:

Tremfya: 100 mg/mL (1 mL) [contains polysorbate 80]

Administration: Adult

IV: Administer diluted solution over at least 1 hour using an infusion set with an in-line, sterile, nonpyrogenic, low-protein-binding filter (pore size 0.2-micrometer). Do not infuse with other medicinal products.

SUBQ: Administer SUBQ into front of thighs, lower abdomen (except for 2 inches around navel), or back of upper arms; do not inject into areas where the skin is tender, bruised, red, hard, thick, scaly, or affected by psoriasis. When administering the 400 mg dose, administer as 2 consecutive 200 mg injections. Press and hold the prefilled pen (200 mg per 2 mL) firmly against the skin until 2 clicks are heard (~10 seconds) and the plunger rod stops moving and fills the viewing window. Push the one-press injector (100 mg/mL) against the skin at a comfortable rate until the handle is fully depressed. Some resistance may be felt during injection; do not lift the one-press injector until the injection is complete.

Medication Guide and/or Vaccine Information Statement (VIS)

An FDA-approved patient medication guide, which is available with the product information and as follows, must be dispensed with this medication;

Tremfya: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761061s009lbl.pdf#page=15

Use: Labeled Indications

Crohn disease: Treatment of moderately to severely active Crohn disease in adults.

Plaque psoriasis: Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Psoriatic arthritis: Treatment of active psoriatic arthritis in adults.

Ulcerative colitis, moderate to severe: Treatment of moderately to severely active ulcerative colitis in adults.

Metabolism/Transport Effects

None known.

Drug Interactions

(For additional information: Launch drug interactions program)

Note: Interacting drugs may **not be individually listed below** if they are part of a group interaction (eg, individual drugs within “CYP3A4 Inducers [Strong]” are NOT listed). For a complete list of drug interactions by individual drug name and detailed management recommendations, use the drug interactions program by clicking on the “Launch drug interactions program” link above.

Abrocitinib: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk X: Avoid combination*

Anifrolumab: Biologic Anti-Psoriasis Agents may enhance the immunosuppressive effect of Anifrolumab. *Risk X: Avoid combination*

Antithymocyte Globulin (Equine): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Antithymocyte Globulin (Equine). Specifically, these effects may be unmasked if the dose of immunosuppressive therapy is reduced. Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Antithymocyte Globulin (Equine). Specifically, infections may occur with greater severity and/or atypical presentations. *Risk C: Monitor therapy*

Baricitinib: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Baricitinib. *Risk X: Avoid combination*

BCG Products: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of BCG Products. Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of BCG Products. *Risk X: Avoid combination*

Belimumab: May enhance the immunosuppressive effect of Biologic Anti-Psoriasis Agents. Management: Consider alternatives to the use of belimumab with other biologic therapies. Monitor closely for increased toxicities related to additive immunosuppression (ie, infection, malignancy) if combined. *Risk D: Consider therapy modification*

Brincidofovir: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Brincidofovir. *Risk C: Monitor therapy*

Brivudine: May enhance the adverse/toxic effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk X: Avoid combination*

Chikungunya Vaccine (Live): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Chikungunya Vaccine (Live). Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Chikungunya Vaccine (Live). *Risk X: Avoid combination*

Cladribine: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Cladribine. *Risk X: Avoid combination*

Coccidioides immitis Skin Test: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the diagnostic effect of Coccidioides immitis Skin Test. Management: Consider discontinuing therapeutic immunosuppressants several weeks prior to coccidioides immitis skin antigen testing to increase the likelihood of accurate diagnostic results. *Risk D: Consider therapy modification*

COVID-19 Vaccine (Inactivated Virus): Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of COVID-19 Vaccine (Inactivated Virus). *Risk C: Monitor therapy*

COVID-19 Vaccine (mRNA): Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of COVID-19 Vaccine (mRNA). Management: Give a 3-dose primary series for all patients aged 6 months and older taking immunosuppressive medications or therapies. Booster doses are recommended for certain age groups. See CDC guidance for details. *Risk D: Consider therapy modification*

COVID-19 Vaccine (Subunit): Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of COVID-19 Vaccine (Subunit). *Risk C: Monitor therapy*

Dengue Tetravalent Vaccine (Live): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Dengue Tetravalent Vaccine (Live). Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Dengue Tetravalent Vaccine (Live). *Risk X: Avoid combination*

Denosumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Denosumab. Management: Consider the risk of serious infections versus the potential benefits of coadministration of denosumab and immunosuppressants. If combined, monitor for signs/symptoms of serious infections. *Risk D: Consider therapy modification*

Deucravacitinib: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk X: Avoid combination*

Efgartigimod Alfa: May diminish the therapeutic effect of Fc Receptor-Binding Agents. *Risk C: Monitor therapy*

Etrasimod: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk X: Avoid combination*

Filgotinib: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk X: Avoid combination*

Inebilizumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Inebilizumab. *Risk C: Monitor therapy*

InFLIXimab: May enhance the immunosuppressive effect of Biologic Anti-Psoriasis Agents. *Risk X: Avoid combination*

Influenza Virus Vaccines: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Influenza Virus Vaccines. Management: Administer influenza vaccines at least 2 weeks prior to initiating immunosuppressants if possible. If vaccination occurs less than 2 weeks prior to or during therapy, revaccinate 2 to 3 months after therapy discontinued if immune competence restored. *Risk D: Consider therapy modification*

Leflunomide: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Leflunomide. Management: Increase the frequency of chronic monitoring of platelet, white blood cell count, and hemoglobin or hematocrit to monthly, instead of every 6 to 8 weeks, if leflunomide is coadministered with immunosuppressive agents. *Risk D: Consider therapy modification*

Mumps- Rubella- or Varicella-Containing Live Vaccines: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Mumps- Rubella- or Varicella-Containing Live Vaccines. Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Mumps- Rubella- or Varicella-Containing Live Vaccines. *Risk X: Avoid combination*

Nadofaragene Firadenovec: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Nadofaragene Firadenovec. Specifically, the risk of disseminated adenovirus infection may be increased. *Risk X: Avoid combination*

Natalizumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Natalizumab. *Risk X: Avoid combination*

Ocrelizumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Ocrelizumab. *Risk C: Monitor therapy*

Ofatumumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Ofatumumab. *Risk C: Monitor therapy*

Pidotimod: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Pidotimod. *Risk C: Monitor therapy*

Pimecrolimus: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Pimecrolimus. *Risk X: Avoid combination*

Pneumococcal Vaccines: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Pneumococcal Vaccines. *Risk C: Monitor therapy*

Poliovirus Vaccine (Live/Trivalent/Oral): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Poliovirus Vaccine (Live/Trivalent/Oral). Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Poliovirus Vaccine (Live/Trivalent/Oral). *Risk X: Avoid combination*

Polymethylmethacrylate: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the potential for allergic or hypersensitivity reactions to Polymethylmethacrylate. Management: Use caution when considering use of bovine collagen-containing implants such as the polymethylmethacrylate-based Bellafill brand implant in patients who are receiving immunosuppressants. Consider use of additional skin tests prior to administration. *Risk D: Consider therapy modification*

Rabies Vaccine: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Rabies Vaccine. Management: Complete rabies vaccination at least 2 weeks before initiation of immunosuppressant therapy if possible. If combined, check for rabies antibody titers, and if vaccination is for post exposure prophylaxis, administer a 5th dose of the vaccine. *Risk D: Consider therapy modification*

Ritlecitinib: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Ritlecitinib. *Risk X: Avoid combination*

Rozanolixizumab: May diminish the therapeutic effect of Fc Receptor-Binding Agents. *Risk C: Monitor therapy*

Ruxolitinib (Topical): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Ruxolitinib (Topical). *Risk X: Avoid combination*

Sipuleucel-T: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Sipuleucel-T. Management: Consider reducing the dose or discontinuing the use of immunosuppressants prior to initiating sipuleucel-T therapy. *Risk D: Consider therapy modification*

Sphingosine 1-Phosphate (S1P) Receptor Modulator: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk C: Monitor therapy*

Tacrolimus (Topical): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Tacrolimus (Topical). *Risk X: Avoid combination*

Talimogene Laherparepvec: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Talimogene Laherparepvec. Specifically, the risk of infection from the live, attenuated herpes simplex virus contained in talimogene laherparepvec may be increased. *Risk X: Avoid combination*

Tertomotide: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Tertomotide. *Risk X: Avoid combination*

Tofacitinib: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Tofacitinib. Management: Coadministration of tofacitinib with potent immunosuppressants is not recommended. Use with non-biologic disease-modifying antirheumatic drugs (DMARDs) was permitted in psoriatic arthritis clinical trials. *Risk X: Avoid combination*

Typhoid Vaccine: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Typhoid Vaccine. Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Typhoid Vaccine. *Risk X: Avoid combination*

Ublituximab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Ublituximab. *Risk C: Monitor therapy*

Upadacitinib: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Upadacitinib. *Risk X: Avoid combination*

Vaccines (Live): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Vaccines (Live). Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Vaccines (Live). *Risk X: Avoid combination*

Vaccines (Non-Live/Inactivated/Non-Replicating): Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Vaccines (Non-Live/Inactivated/Non-Replicating). Management: Give non-live/inactivated/non-replicating vaccines at least 2 weeks prior to starting immunosuppressants when possible. Patients vaccinated less than 14 days before or during therapy should be revaccinated at least 2 to 3 months after therapy is complete. *Risk D: Consider therapy modification*

Yellow Fever Vaccine: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Yellow Fever Vaccine. Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Yellow Fever Vaccine. *Risk X: Avoid combination*

Zoster Vaccine (Live/Attenuated): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Zoster Vaccine (Live/Attenuated). Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Zoster Vaccine (Live/Attenuated). *Risk X: Avoid combination*

Reproductive Considerations

In general, patients who may become pregnant should use effective contraception while using biologic therapy for the treatment of psoriasis (Smith 2020; Yeung 2020). Treatment algorithms are available for use of biologics in patients with inflammatory bowel disease planning to become pregnant (Mahadevan 2019).

Pregnancy Considerations

Guselkumab is a humanized monoclonal antibody (IgG_1). Human IgG crosses the placenta. Fetal 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).

Outcome data following maternal use of guselkumab during pregnancy are limited (Al-Khawaga 2021; Dernoncourt 2023). Agents other than guselkumab are currently recommended for the treatment of psoriasis in pregnancy (AAD/NPF [Menter 2019]; Yeung 2020). Treatment algorithms are available for use of biologics in pregnant patients with inflammatory bowel disease (Mahadevan 2019).

Data collection to monitor pregnancy and infant outcomes following exposure to guselkumab is ongoing. Patients exposed to guselkumab during pregnancy are encouraged to enroll themselves in the pregnancy registry by visiting www.mothertobaby.org/ongoing-study/tremfya-guselkumab, calling 1-877-311-8972, or emailing MotherToBaby@health.ucsd.edu.

Breastfeeding Considerations

It is not known if guselkumab is present in breast milk.

Guselkumab 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). According to the manufacturer, the decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and benefits of treatment to the mother.

Monitoring Parameters

Prior to therapy start:

• Evaluate for malignancy (especially skin cancer), current or latent infection, lymphadenopathy, ensure age-appropriate vaccinations are up to date, and, in general, no live vaccines are administered within 4 weeks of starting therapy (AAD/NPF [Menter 2019]; EuroGuiDerm [Nast 2024]). Refer to institutional protocols for vaccination and monitoring requirements prior to initiating therapy.

• **Labs:** CBC with differential; complete metabolic panel; bilirubin and LFTs in Crohn disease or ulcerative colitis patients; testing for tuberculosis (TB) infection (latent TB) (eg, Quantiferon Gold) or interferon gamma release assay for TB in patients who have had Bacillus Calmette-Guerin (BCG) vaccine; chest radiograph if testing for TB infection is positive; serologic testing for hepatitis B virus (HBV) (HBsAg, HBsAb, HBAbcore), hepatitis C virus antibody, HIV, pregnancy test, C-reactive protein (AAD/NPF [Menter 2019]; EuroGuiDerm [Nast 2024]).

During therapy:

• Evaluate for infection, malignancy (specifically skin cancer screening, especially for patients who have a history of skin cancer or UV phototherapy), infusion/injection site reactions, and symptoms consistent with posterior reversible encephalopathy syndrome or axial polyneuropathy (AAD/NPF [Menter 2019]; EuroGuiDerm [Nast 2024]).

• **Labs:** CBC and LFTs every 3 to 6 months; bilirubin and LFTs for at least 16 weeks of treatment and then periodically in Crohn disease or ulcerative colitis patients; pregnancy test as needed; yearly testing/chest radiograph for TB in high-risk patients (eg, contact with individuals with TB disease [active TB]) (AAD/NPF [Menter 2019]; EuroGuiDerm [Nast

2024]); hepatitis B carriers should be periodically evaluated for signs/symptoms of active hepatitis B infection (AAD/NPF [Menter 2019]).

After therapy:

• Periodically evaluate patients who are hepatitis B carriers for signs/symptoms of active hepatitis B infection (AAD/NPF [Menter 2019]).

Mechanism of Action

Human IgG1 monoclonal antibody selectively binds with IL-23, thereby reducing serum levels of IL-17A, IL-17F, and IL-22. Guselkumab inhibits the release of proinflammatory cytokines and chemokines.

Pharmacokinetics (Adult Data Unless Noted)

Onset of action: Psoriasis: Response best determined after 12 weeks (AAD/NPF [Menter 2019]).

Distribution: V_d: Crohn disease: 11.4 L; plaque psoriasis: 13.5 L; ulcerative colitis: 10.1 L.

Metabolism: Degraded into small peptides and amino acids via catabolic pathways in the same manner as endogenous IgG.

Bioavailability: SUBQ: ~49%.

Half-life elimination: Crohn disease and ulcerative colitis: 17 days; plaque psoriasis: 15 to 18 days.

Time to peak: SUBQ: 5.5 days.

Brand Names: International

International Brand Names by Country

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Topic 114007 Version 170.0