Cosibelimab-ipdl

An HCP Tool From AIM with Immunotherapy

Cosibelimab-ipdl (Unloxcyt™) is a programmed death ligand-1 (PD-L1)–blocking antibody that inhibits the interaction of PD-L1 with its receptors, PD-1 and B7.1, on T cells. By blocking this pathway, cosibelimab helps prevent tumor cells from suppressing the immune response, enabling T- cells to recognize and destroy cancer cells more effectively. In addition, cosibelimab may enhance antitumor activity by recruiting other immune effector cells that directly target and kill cancer cells.

Cosibelimab is indicated for the treatment of adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced cutaneous squamous cell carcinoma (laCSCC) who are not candidates for curative surgery or curative radiation therapy.

DRUG DOSAGE/ADMINISTRATION

- The recommended dose of cosibelimab is 1200 mg administered as an intravenous infusion over 60 minutes every 3 weeks until disease progression or unacceptable toxicity.

- Cosibelimab is a clear to opalescent, colorless to yellow or slightly brown solution containing one 300 mg/5 mL (60mg/mL), single-dose vial. Discard the vial if the solution is discolored or contains particulate matter. Do not shake the vial.

- Add 20 mL (1,200 mg) to a 250 mL intravenous infusion bag containing 0.9% Sodium Chloride Injection. Cosibelimab is compatible with an infusion bag made of polyolefin or polyvinyl chloride.
    - Mix diluted solution by gentle inversion. Do not shake.
    - Discard any unused portion left in the vial.

- The prepared infusion solution may be stored either:
    - At room temperature up to 25°C (77°F) for no more than 24 hours from the time of preparation until the end of infusion.
    - Under refrigeration at 2°C to 8°C (36°F to 46°) for no more than 24 hours from time of preparation until end of infusion. If refrigerated, allow the diluted solution to come to room temperature prior to administration.
    - Discard after 24 hours.
    - Do not freeze.

- Administration:
    - Visually inspect the infusion bag for particulate matter and discoloration prior to administration. Discard if the solution is discolored or contains particulate matter.
    - Administer by intravenous infusion over 60 minutes through an intravenous line containing a sterile, in-line or add-on 0.2-micron to 0.22-micron filter.
    - Do not administer cosibelimab as an intravenous push or bolus injection.
    - Do not co-administer other drugs through the same infusion line.

SIDE EFFECTS AND THEIR MANAGEMENT

- Because cosibelimab is an immunotherapy that works by enhancing the patient's immune system, most adverse reactions associated with cosibelimab are related to overactivity of the patient's immune system (ie, immune-related adverse events [irAEs]). Various organ systems (often more than one) or tissues may be affected.
- The most common (>10%) adverse reactions were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection.
- Keys to toxicity management:
  - Proactive assessment for early signs/symptoms of toxicity
  - Prompt intervention
  - IrAEs are typically managed with treatment interruption and selective use of corticosteroids
  - In rare instances, toxicity may not be responsive to steroid treatment, and additional immunosuppressive agents may be necessary (infliximab, mycophenolate mofetil, cyclophosphamide, etc)
  - Cosibelimab will likely be held or discontinued depending on severity and/or persistence
  - Referral to an organ specialist should be considered, given that unique testing and management strategies may be required
- IrAEs associated with cosibelimab treatment can be categorized into those that are most common, less common but serious, and others that are easily overlooked.

Care Step Pathways for the management of immune-related AEs associated with cosibelimab

irAE category	**Examples**
Most common	Thyroiditis (hypothyroid, hyperthyroid) Skin toxicities (rash, pruritus)
Less common but serious	Other endocrine (adrenal insufficiency, hypophysitis) Pneumonitis
Late-onset and/or long-lasting easily overlooked	Arthralgia Asthenia Neuropathy Nephritis

AIM WITH IMMUNOTHERAPY FOUNDATION

Management of other AEs associated with PD-1/PD-L1 inhibitor monotherapy

Adverse event	Common symptoms	Common management/anticipatory guidance
Anemia	Weakness, pale skin, irregular heartbeat, shortness of breath, dizziness, cold hands and feet	• Complete laboratory evaluation; rule out other potential causes for symptoms including evaluation of autoimmune hemolytic anemia as clinically appropriate • Anticipate standard dose holds/discontinuations* • Red blood cell transfusion support as needed • Provide close clinical follow-up
Anorexia	Decreased appetite	• Monitor weight; query patient about appetite/eating habits; advise dietary modification if necessary (should improve with time) • Anticipate standard dose holds/discontinuations* • Consider referral to nutrition services for counseling on best food choices to minimize excessive weight loss
Constipation/ abdominal pain	Infrequent stools/ difficulty stooling, abdominal pain	• Consider other causes, such as opioid-induced constipation • Increase fluid, fiber; use laxatives with caution; suggest stool softeners and physical activity • Consider appropriate testing to evaluate bowel obstruction • Anticipate standard dose holds/discontinuations* for Grade 3 and Grade 4 (constipation with manual evacuation indicated, severe abdominal pain, or life-threatening consequences)
Embryo-fetal toxicity	—	• Advise of risk to fetus and recommend use of effective contraception during treatment and for 4 months after cosibelimab is discontinued • Advise patients to tell their HCPs immediately if they or their partner suspect they are pregnant while receiving therapy
Encephalitis	Headache, fever, tiredness, confusion, memory problems, sleepiness, hallucinations, seizures, stiff neck	• New-onset, moderate-to-severe symptoms: rule out infectious or other causes • Consult neurologist, obtain brain MRI, and lumbar puncture • Anticipate standard dose-holds and discontinuations*
Fatigue	Feeling tired; lack of energy	• Query patients regarding energy level; evaluate possible contributory factors, including infection, disease progression, and hematological and metabolic abnormalities; standard supportive care • Anticipate standard dose holds/discontinuations* • Fatigue that interferes with ADLs is concerning and should be evaluated for underlying causes, such as possible endocrinopathy

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Management of other AEs associated with PD-1/PD-L1 inhibitor monotherapy

Adverse event	Common symptoms	Common management/anticipatory guidance
Headache	Head pain	• Need to rule out brain metastases, encephalitis, or hypophysitis; otherwise, standard supportive care (should improve with time) • Headache occurring in conjunction with fatigue could be indicative of hypophysitis; obtain MRI of brain with pituitary slices/pituitary protocol to confirm/rule out • Anticipate standard dose holds/discontinuations*
Hypoparathyroidism	Tingling or twitching sensations, muscle aches, weakness, dry skin, depression, confusion, heart arrhythmia, fainting	• Complete laboratory evaluation (calcium, parathyroid hormone, albumin, etc.); rule out other potential causes for symptoms • Obtain urgent endocrinology referral • Standard dose holds/discontinuations* • IV calcium may be required, followed by oral therapy • Provide close clinical follow-up
Infusion reaction	Chills/shaking, back pain, itching, flushing, difficulty breathing, hypotension, fever	• Monitor patients for signs and symptoms. For grade 1 or 2 reactions, slow or interrupt infusion and administer premedications. For grade 3 or 4 reactions, stop infusion and consider permanently discontinuing cosibelimab • When appropriate, consider desensitization protocols
Insomnia	Difficulty falling or staying asleep	• Counsel patients on sleep hygiene; prescription medications as clinically indicated • Anticipate standard dose holds/discontinuations*
Lower respiratory tract infection (pneumonia)	Shortness of breath, productive or dry cough, fever, sweating, or chills	• Chest X-ray, oxygen levels, infectious diseases workup • Chest CT to evaluate for and rule out immune-related pneumonitis • Antimicrobials (if appropriate), antipyretics, supportive care • Anticipate standard treatment holds/discontinuations*
Meningitis (aseptic)	Headache, photophobia, skin neck, nausea and vomiting, fever, cognition typically unaffected	• Rule out infectious, endocrine/metabolic, or other causes • Consult neurology, obtain brain MRI and consider lumbar puncture • Anticipate standard dose-holds and discontinuations* • Anticipate requirement for corticosteroids, empiric antimicrobials, supportive care, and hospitalization, depending on severity • Permanently discontinue cosibelimab for Grades 2, 3, or 4

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Management of other AEs associated with PD-1/PD-L1 inhibitor monotherapy

Adverse event	Common symptoms	Common management/anticipatory guidance
Myocarditis	Shortness of breath; arrhythmia; light-headedness; chest pain; fatigue; nausea; edema	• Obtain baseline ECG • Assess cardiac biomarkers (BNP; troponin) • Control cardiac diseases (and risk factors) optimally • Consult cardiologist and consider corticosteroids if myocarditis is suspected • Add additional immunosuppressive agents in severe, refractory cases • Institute standard dose holds/discontinuations (in consultation with cardiologist)
Nausea/vomiting	Vomiting, queasiness, RUQ or LUQ pain	• Rule out brain metastases, gastroenteritis • Provide standard supportive care, since it is adequate in most cases • Check LFTs/lipase/amylase if hepatotoxicity or pancreatitis are suspected • Anticipate standard dose holds/discontinuations*
Upper respiratory tract infection	Cough, runny nose, sore throat, nasal congestion	• Evaluate potential causes—a dry cough and shortness of breath would increase concern for pneumonitis • Standard supportive care • Anticipate standard treatment holds*
Vasculitis	Pain, swelling, vein visibility/ rash, cyanosis, unexplained fever, pleuritic pain, cough, wheezing, or hemoptysis	• Work-up for vasculitis (urinalysis, angiography, other imaging, blood work), rule out other causes • Consult rheumatology • Anticipate standard dose holds/discontinuations* and requirement for high-dose corticosteroids
Vision changes	Eye redness, pain, blurred vision, photophobia	• Test and evaluate for uveitis and episcleritis (by ophthalmologist, preferably) • Urgency of ophthalmology referral increases with grade • G1: continue immunotherapy, use artificial tears • G2: hold immunotherapy; ophthalmic and systemic corticosteroids (under ophthalmologist guidance) • G3 or G4: permanently discontinue immunotherapy; treatment by ophthalmologist to include ophthalmic and systemic corticosteroids

In general, withhold cosibelimab for severe (Grade 3) irAEs. Permanently discontinue for life-threatening (Grade 4) irAEs, recurrent severe (Grade 3) that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to <10 mg prednisone (or equivalent) per day within 12 weeks of initiating steroids.

*Exceptions to above recommendation include withholding cosibelimab for the following Grade 2 irAEs: pneumonitis, colitis, neurologic toxicities, and nephritis with renal dysfunction. In addition, cosibelimab should be withheld for ANY suspicion (regardless of grade) of myocarditis or exfoliative dermatologic condition.

CLINICAL PEARLS

- It is important to monitor laboratory values at the start of treatment, periodically during treatment, and as indicated clinically. Laboratory values commonly monitored include: CBC w/ or w/o differential, creatinine, alkaline phosphatase, AST/ALT, bilirubin (direct/total), sodium, potassium, calcium, magnesium, thyroid function (TSH and free T4), and glucose. See individual irAE CSPs for more detail on laboratory monitoring
- Though rare, cosibelimab-related irAEs may occur at any time, including after treatment completion or discontinuation
- Patients sometimes experience signs/symptoms that they think are due to “flu” or a cold, but that actually represent an irAE or an infusion reaction
- Thyroid related endocrinopathies are the most common immune-related AE with cosibelimab. It is important to obtain baseline thyroid functions tests (TSH and free T4) and monitor regularly during treatment, and for up to two years after treatment completion or discontinuation.
- Unlike other irAEs, endocrinopathies usually do not resolve and may require lifelong hormone replacement therapy
- IrAEs have different time courses. New irAEs may become apparent upon tapering of corticosteroids used to treat an earlier onset irAE, since the new irAE can be suppressed or masked by immunosuppressive therapy. Therefore, during the taper period, patients should be advised to be on the lookout for early signs of new irAEs as well as recurrence of the original irAE that was being treated
- HCPs should encourage patients to carry information about their cosibelimab regimen with them at all times. This might be a wallet card, or at least emergency phone numbers and the side effects associated with the regimen. You may suggest patients paperclip the wallet and insurance cards together so information about their regimen will be shared whenever they show their insurance card. Here is an example of a wallet card: https://www.ons.org/sites/default/files/2025-02/25-immunotherapy-wallet-card.pdf
- Advise patients to take pictures of any skin changes for documentation

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QUESTIONS & ANSWERS

Q. **How long will patients stay on cosibelimab?**

A. The prescribing information indicates continuation until disease progression or unacceptable toxicity.

Q. **Is PD-L1 testing required for patients to be eligible to receive cosibelimab?**

A. No PD-L1 testing is required for patients receiving cosibelimab.

Q. **Are there standard dosage reductions for irAEs associated with cosibelimab?**

A. There are no dosage reductions for irAEs associated with cosibelimab. The dose is either held until the irAE resolves sufficiently (typically to Grade 0 or Grade 1) or, if the irAE is severe enough, cosibelimab may be discontinued permanently.

Q. **How do I counsel my patients about immunizations?**

A. That's a logical question, given that the checkpoint inhibitors alter the immune response. Advise your patients not to receive live vaccines (eg, measles, mumps, and rubella and the varicella vaccine [Zostavax®]) because they have not been evaluated in this setting. The use of attenuated vaccines has been and continues to be evaluated. Counsel patients to discuss all immunizations with the oncology team prior to administration so the benefits and risks can be weighed on an individual basis. For example, SHINGRIX®, approved in 2017, is an attenuated (non-live) varicella vaccine; its use should be discussed with the oncology team if a recommendation is being made for the patient to receive the injection series. Patients should be encouraged to get the inactivated influenza vaccine annually. The nasal spray flu vaccine is a live attenuated influenza vaccine and should not be administered to patients treated with immune checkpoint inhibitors.

PATIENT RESOURCES

ADDITIONAL INFORMATION RESOURCES

AIM at Skin Cancer (Ask a Nurse program, patient symposia, drug resources, etc)
https://www.aimatskincancer.org/

American Cancer Society
https://www.cancer.org/

FINANCIAL ASSISTANCE

UNLOXCYT SUPPORT™
1-855-865-9994
www.unloxcyt.com/support-resources

Cancer Financial Aid Coalition
Facilitates communication, educates and advocates for patients.
www.cancerfac.org

Centers for Medicare and Medicaid Services (CMS)
Apply to determine if you are eligible for government assistance.
www.cms.gov or www.medicare.gov
800-633-4227

Lazarex Foundation
Provides assistance with travel costs for clinical trial participation. Ask your social work counselor for a referral if you have been consented to a clinical trial for melanoma.
www.lazarex.org

Needymeds
Database to search for free or low-cost medications, help with medical transportation and other resources.
www.needymeds.org

Patient Advocate Foundation
Provides assistance with mediation, financial stability, and other assistance. Funds subject to availability. Patients must meet their eligibility for financial assistance.
www.patientadvocate.org
800-532-5274

PRESCRIPTION ASSISTANCE

Medicine Assistance Tool
Database to search for patient assistance resources offered by pharmaceutical companies.
www.medicineassistancetool.org/

Patient Advocate Foundation Co-Pay Relief
Provides direct financial support to patients who medically qualify.
www.copays.org
1-866-512-3861

Good Days
Formerly known as the Chronic Disease Fund. Provides assistance with insurance co-pays, and prescription medicationswww.mygooddays.org

HealthWell Foundation
For patients who cannot afford insurance premiums, co-payments, co-insurance, or other out-of-pocket health care costs. Patient must also meet eligibility for financial assistance.
www.healthwellfoundation.org or
grants@healthwellfoundation.org
1-800-675-8416

The Assistance Fund, Inc
Provides prescription copay and financial assistance, including health insurance premiums.
www.theassistancefund.org
1-855-845-3663

PAN Foundation
Provides financial assistance to cover out-of-pocket treatment costs.
www.panfoundation.org
1-866-316-PANF (7263)

Patient Assistance Program
Comprehensive database of patient assistance programs offering free medications.
www.rxassist.org
info@rxassist.org

HOUSING

American Cancer Society – Hope Lodge

Provides free housing during treatment appointments. Requires a referral from your social worker.

www.cancer.org/

1-800-227-6333

TRANSPORTATION (AIR AND GROUND)

Medicaid

Ground transportation only. Sets up rides and provides mileage reimbursement for Medicaid patients only.

1-877-633-8747

Mercy Medical Angels

Provides free medical transportation (flights, gas cards, bus and train tickets) for patients with financial needs who need to travel more than 50 miles. Patients must meet their eligibility for financial assistance.

www.mercymedical.org/

Pilots for Patients

Provides free flights to people in need of medical treatment. Patient must be medically stable to fly and be ambulatory. Ask your social worker about a referral.

www.pilotsforpatients.org

318-322-5112

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