Cemiplimab

An HCP Tool From AIM with Immunotherapy

Programmed death receptor-1 (PD-1) is a protein expressed on the surface of T cells and acts as a negative regulator of T-cell activation and proliferation. In other words, PD-1 activation "turns the immune system off," essentially acting as a brake. This type of inhibitory capability is necessary to prevent lethal inflammation, severe immune reactions and autoimmunity. However, cancer cells exploit this system. Due to PD-1's role as a preventer of an uncontrolled or extremely dangerous immune response, PD-1 and similar regulators are called immune checkpoints.

Programmed death ligand-1 (PD-L1) is a protein expressed on the surface of normal cells that helps regulate immune responses by interacting with the PD-1 receptor on T cells. This helps prevent autoimmune reactions. To exploit the PD-1/PD-L1 system and avoid immune detection, some tumor cells will express PDL1 on their cell surface just like normal cells, allowing them to interact with PD-1 on T cells and "turn off" the immune system. With PD-L1, the cancer cells prevent identification and elimination by T cells.

Cemiplimab (Libtayo®) is a PD-1 monoclonal antibody checkpoint inhibitor. Cemiplimab selectively binds to PD-1, blocking the PD-1/PD-L1 interaction and thereby "exposing" cancer cells and "turning on" the immune system.

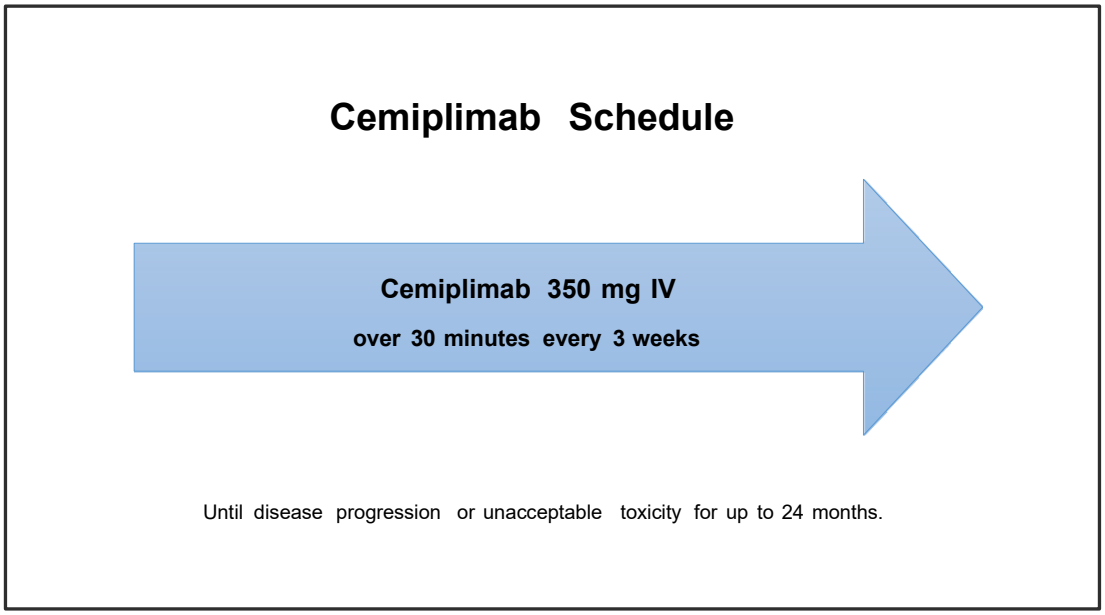
Cemiplimab has several indications. It is indicated for the treatment of patients with metastatic basal cell carcinoma (mBCC) or locally advanced BCC (laBCC) that have been previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate. Use of cemiplimab for BCC does not require testing of PD-L1 expression.

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

Cemiplimab is also indicated for non-small cell lung cancer (NSCLC) in combination with platinum-based chemotherapy for the first-line treatment of adult patients with NSCLC with no EGFR, ALK or ROS1 aberrations and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic. It is approved as a single agent for the first-line treatment of adult patients with NSCLC whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations, and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic.

DRUG DOSAGE/ADMINISTRATION

- The recommended dose of cemiplimab (Libtayo®) is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity for up to 24 months.



- Cemiplimab is a clear to slightly opalescent, colorless to pale yellow solution that may contain trace amounts of translucent to white particles. Discard the vial if the solution is cloudy, discolored, or contains extraneous particulate matter other than trace amounts of translucent to white particles
- Withdraw 7 mL from a vial and dilute with 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection,
    - USP to a final concentration between 1 mg/mL to 20 mg/mL. Mix diluted solution by gentle inversion. Do NOT shake. Discard any unused medicinal product or waste material
- Administer by intravenous infusion over 30 minutes through an intravenous line containing a sterile, in-line or add-on 0.2-micron to 5-micron filter.

SIDE EFFECTS AND THEIR MANAGEMENT

- Because cemiplimab is an immunotherapy that works by enhancing the patient's immune system, most adverse reactions associated with cemiplimab 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.
- 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)
    - Cemiplimab will likely be held or discontinued depending on severity and/or persistence
    - Referral to organ specialist should be considered, given that unique testing and management strategies may be required
- IrAEs associated with cemiplimab treatment can be categorized into those that are most common, less common but serious, and others that are easily overlooked. (Table 1; Appendix 1). Other adverse events associated with cemiplimab therapy are listed in Appendix 2

Table 1. Care Step Pathways for the management of immune-related AEs associated with cemiplimab monotherapy.

IrAEs category	Examples
Most common	Musculoskeletal pain Skin toxicities (pruritis, rash, etc) Gastrointestinal toxicity– Diarrhea and colitis Thyroiditis Hepatic toxicities
Less common but serious	Additional endocrinopathies » Hypophysitis (pituitary) » Adrenal insufficiency (adrenalitis) » Diabetes » Pneumonitis Myocarditis
Easily overlooked	Arthralgia/arthritis Mucositis/xerostomia Neuropathy Nephritis

AIM WITH IMMUNOTHERAPY FOUNDATION

Management of other AEs associated with PD-1 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 • Anticipate standard dose holds/discontinuations* • Provide close clinical follow-up • Evaluate growth factor support or red blood cell transfusions as needed
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 avoid 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 cemiplimab is discontinued • Advise patients to tell their HCPs immediately if they or their partners suspect they are pregnant while taking 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 • Counsel neurologist, obtain brain MRI, and lumbar puncture • Anticipate standard dose-holds and discontinuations*

AIM WITH IMMUNOTHERAPY FOUNDATION

Management of other AEs associated with PD-1 inhibitor monotherapy

Adverse event	Common symptoms	Common management/anticipatory guidance
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
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. For grade 3 or 4 reactions, stop infusion and permanently discontinue cemiplimab.
Insomnia	Difficulty falling or staying asleep	• Counsel patients on good sleep habits; prescription medications can be used if needed (should improve over time) • Anticipate standard dose holds/discontinuations*
Lower respiratory tract infection (pneumonia)	Shortness of breath, productive or dry cough, fever, sweating, or chills	• Chest Xray, oxygen levels, infectious diseases workup • Differential from irAE pneumonitis • Antimicrobials (if appropriate), antipyretics, supportive care • Anticipate standard treatment holds

AIM WITH IMMUNOTHERAPY FOUNDATION

Management of other AEs associated with PD-1 inhibitor monotherapy

Adverse event	Common symptoms	Common management/anticipatory guidance
Meningitis (aseptic)	Headache, photophobia, skin neck, nausea and vomiting, fever, cognition typically unaffected	• Rule out infectious, endocrine/metabolic, or other causes • Counsel neurologist, obtain brain MRI and lumbar puncture • Anticipate standard dose-holds and discontinuations* • Anticipate requirement for corticosteroids, empiric antimicrobials, supportive care, and hospitalization, depending on severity • Permanently discontinue cemiplimab for Grades 2,3, or 4
Nausea/vomiting	Vomiting, queasiness, RUQ or LUQ pain	• Rule out brain metastases and 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

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/ differential, creatinine, alkaline phosphatase, AST/ALT, bilirubin (direct/total), sodium, potassium, calcium, magnesium, thyroid function, and glucose. See individual irAE CSPs for more detail on laboratory monitoring
- Cemiplimab-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
- Endocrinopathies often present with vague symptoms (fatigue, headache, and/or depression) that can easily be overlooked or initially misdiagnosed. Hypervigilance and follow-up is important on the part of both HCPs and patients
- Endocrinopathies tend to occur somewhat more commonly with cemiplimab or other PD-1 inhibitor therapies than with ipilimumab monotherapy
- 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 cemiplimab regimen with them at all times. This might be the cemiplimab-specific wallet card, or at least emergency phone numbers and the side effects associated with the regimen. You may suggest that they paperclip the wallet and insurance cards together so information about their regimen will be shared whenever they show their insurance card. Here is the link to the wallet card: https://www.libtayo.com/resources/pdf/patient-wallet-card.pdf
- Advise patients to take pictures of any skin changes for documentation

AIM WITH IMMUNOTHERAPY FOUNDATION

QUESTIONS & ANSWERS

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

A. The prescribing information indicates until disease progression or unacceptable toxicity for up to 24 months.

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

A. No PD-L1 testing is required for patients receiving cemiplimab for BCC but it is required for NSCLC.

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

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

Q. **Does the safety profile of cemiplimab differ when it is used in various tumor types?**

A. Generally, the safety profile of cemiplimab is similar across tumor types. However, the context may be different—patients with other tumor types may have differing comorbidities or underlying organ dysfunction. For example, lung cancer patients may have underlying lung disease that will exacerbate shortness of breath associated with pneumonitis. The side-effect profile may vary if given as monotherapy or in combination with pneumonitis.

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

Regeneron Pharmaceuticals, Inc
Libtayo Surround Program
Libtayo injection (cemiplimab-rwlc)
1-877-734-6777
https://www.libtayohcp.com/libtayo-surround

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. Patient must meet their eligibility for financial assistance.
www.patientadvocate.org
800-532-5274

The Sam Fund for Young Adult Survivors of Cancer
Assists cancer survivors ages 21-39 with their transition into post-treatment life. This program distributes grants and scholarships in an effort to enable survivors to pursue goals.
www.thesamfund.org
info@thesamfund.org

PRESCRIPTION ASSISTANCE

CancerCare Co-Payment Assistance Foundation
Helps with the cost of medication. Availability of funds for patients with Stage IV melanoma subject to availability.
www.cancercarecopay.org
1-866-552-6729

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. Availability of funds for patients with Stage IV melanoma subject to availability.
www.copays.org
1-866-512-3861

Good Days
Formerly known as the Chronic Disease Fund. Provides assistance with insurance co-pays, and prescription medications. Availability of funds for patients with Stage IV melanoma subject to availability.
www.mygooddays.org

HealthWell Foundation
For patients who cannot afford insurance premiums, co-payments, co-insurance, or other out-of-pocket health care costs. Availability of funds for patients with Stage IV melanoma subject to availability. 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. Availability of funds for patients with Stage IV melanoma subject to availability.
www.theassistancefund.org
1-855-845-3663

PAN Foundation
Provides financial assistance to cover out-of-pocket treatment costs. Availability of funds for patients with Stage IV melanoma subject to availability.
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

ADDITIONAL RESOURCES

Boutros C, Tarhini A, Routier E, et al. Safety profiles of anti-CTLA-4 and anti-PD-1 antibodies alone and in combination. *Nat Rev Clin Oncol*. 2016;13:473-486. doi:10.1038/nrclinonc.2016.58

Brahmer JR, Abu-Sbeih H, Ascierto PA, et al. Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immune checkpoint inhibitor-related adverse events. *J Immunother Cancer*. 2021;9(6):e002435. doi:10.1136/jitc-2021- 002435

Chen P, Li J, Tan H. Progress and challenges of immune checkpoint inhibitor-induced hypophysitis. *J Clin Med.* 202315;12(10):3468. doi:10.3390/jcm12103468

Cui K, Wang Z, Zhang Q, Zhang X. Immune checkpoint inhibitors and adrenal insufficiency: a large-sample case series study. *Ann Transl Med*. 2022;10(5):251. doi:10.21037/atm-21-7006

Dadu R, Zobniw C, Diab A. Managing adverse events with immune checkpoint agents. *Cancer J*. 2016;22:121-129. doi:10.1097/PPO.0000000000000186

Druce I, Tawagi K, Shaw JLV, Ibrahim A, Lochnan H, Ong M. Routine screening for central and primary adrenal insufficiency during immune-checkpoint inhibitor therapy: An endocrinology perspective for oncologists. *Curr Oncol*. 2022;29(7):4665-4677. doi:10.3390/curroncol29070370

Elia G, Ferrari SM, Galdiero MR, et al. New insight in endocrine-related adverse events associated to immune checkpoint blockade. *Best Pract Res Clin Endocrinol Metab*. 2020;34(1):101370. doi:10.1016/j.beem.2019.101370

Guidon AC, Burton LB, Chwalisz BK, et al. Consensus disease definitions for neurologic immune-related adverse events of immune checkpoint inhibitors. *J Immunother Cancer*. 2021;9(7):e002890. doi:10.1136/jitc-2021-002890

Herrmann SM, Perazella MA. Immune checkpoint inhibitors and immune-related adverse renal events. *Kidney Int Rep*. 2020;5(8):1139-1148. doi: 10.1016/j.ekir.2020.04.018

Hughes MS, Molina GE, Chen ST, et al. Budesonide treatment for microscopic colitis from immune checkpoint inhibitors. *J Immunother Cancer*. 2019;7(1):292. doi: 10.1186/s40425-019-0756-0

Kelly-Goss MR, Badran YR, Dougan M. Update on immune checkpoint inhibitor enterocolitis. *Curr Gastroenterol Rep*. 2022;24(12):171-181. doi:10.1007/s11894-022-00852-7

Kumar V, Chaudhary N, Garg M, Floudas CS, Soni P, Chandra AB. Current diagnosis and management of immune related adverse events (irAEs) induced by immune checkpoint inhibitor therapy. *Front Pharmacol*. 2017;8:49. [Published correction appears in Front Pharmacol. 2017;8:311]. doi:10.3389/fphar.2017.00049

Libtayo® [package insert]. Prescribing information. Regeneron Pharmaceuticals Inc; 2023. Available at: https://www.regeneron.com/downloads/libtayo_fpi.pdf

Losurdo G, Angelillo D, Favia N, et al. Checkpoint inhibitor-induced colitis: An update. *Biomedicines*. 2023;11(5):1496. doi:10.3390/biomedicines11051496

Liu Z, Zhu Y, Xie H, Zou Z. Immune-mediated hepatitis induced by immune checkpoint inhibitors: Current updates and future perspectives. *Front Pharmacol*. 2023;13:1077468. doi:10.3389/fphar.2022.1077468

McGettigan S, Rubin KM. Managing adverse events with PD-1 inhibitor therapy of advanced melanoma: consensus statements from the faculty of the melanoma nursing initiative. *Clin J Oncol Nurs*. 2017;21(Suppl):42-51. doi:10.1188/17.CJON.S4.42-51

Naidoo J, Page DB. Li BT, et al. Toxicities of the anti-PD-1 and anti-PD-L1 immune checkpoint inhibitor antibodies. *Ann Oncol*. 2015;26:2375-2391. doi:10.1093/annonc/mdv383

Nicolaides S, Boussioutas A. Immune-related adverse events of the gastrointestinal system. *Cancers (Basel)*. 2023;15(3):691. doi:10.3390/cancers15030691

Nishijima TF, Shachar SS, Nyrop KA, Muss HB. Safety and tolerability of PD-1/PD-L1 inhibitors compared with chemotherapy in patients with advanced cancer: a meta-analysis. *Oncologist*. 2017;22:470-479. doi:10.1634/theoncologist.2016-0419

Peeraphatdit TB, Wang J, Odenwald MA, Hu S, Hart J, Charlton MR. Hepatotoxicity from immune checkpoint inhibitors: A systematic review and management recommendation. *Hepatology*. 2020;72(1):315-329. doi:10.1002/hep.31227

Percik R, Criseno S, Adam S, Young K, Morganstein DL. Diagnostic criteria and proposed management of immune-related endocrinopathies following immune checkpoint inhibitor therapy for cancer. *Endocr Connect*. 2023;12(5):e220513. doi:10.1530/EC-22-0513

Puzanov I, Diab A, Abdallah K, et al. Managing toxicities associated with immune checkpoint inhibitors: consensus recommendations from the Society for Immunotherapy of Cancer (SITC) Toxicity Management Working Group. *J Immunother Cancer*. 2017;5:95. doi:10.1186/s40425-017-0300-z

Schneider BJ, Naidoo J, Santomasso BD et al. Management of immune-related adverse events in patients treated with immune checkpoint inhibitor therapy: ASCO guideline update. *J Clin Oncol*. 2021;39:4073-4126. doi:10.1200/JCO.21.01440

Schneider BJ, Lacchetti C, Bollin K. Management of the top 10 most common immune-related adverse events in patients treated with immune checkpoint inhibitor therapy. *JCO Oncol Pract*. 2022;18(6):431-444. doi:10.1200/OP.21.00776

Schoenfeld SR, Aronow ME, Leaf RK, Dougan M, Reynolds KL. Diagnosis and management of rare immune-related adverse events. *Oncologist*. 2020;25(1):6-14. doi:10.1634/theoncologist.2019-0083

Spagnolo CC, Giuffrida G, Cannavò S, et al. Management of endocrine and metabolic toxicities of immune-checkpoint inhibitors: From clinical studies to a real-life scenario. *Cancers (Basel)*. 2022;15(1):246. doi:10.3390/cancers15010246

Spain L, Diem S, Larkin J. Management of toxicities of immune checkpoint inhibitors. *Cancer Treat Rev*. 2016;44:51-60. doi:10.1016/j.ctrv.2016.02.001

Stratigos AJ, Sekulic A, Peris K, et al. Cemiplimab in locally advanced basal cell carcinoma after hedgehog inhibitor therapy: an open-label, multi-centre, single-arm, phase 2 trial. *Lancet Oncol*. 2021;22(6):848-857. doi:10.1016/S1470-2045(21)00126-1

Thompson JA, Schneider BJ, Brahmer J, et al. NCCN Guidelines Insights: Management of immunotherapy-related toxicities, version 1. 2020: Featured updates to the NCCN guidelines. *J Natl Compr Canc Netw*. 2020;18(3):230-241. doi:10.6004/jnccn.2020.0012

Weber JS, Postow M, Lao CD, Schadendorf D. Management of adverse events following treatment with anti-programmed death-1 agents. *Oncologist*. 2016;21:1230-1240. doi:10.1634/theoncologist.2016-0055

Wolf P, Scherer T. Clinical challenges in the management of endocrine side effects of immuno-oncological therapies. 2022;15:72–75(memo). https://doi.org/10.1007/s12254-021-00773-7

Wright JJ, Johnson DB. Approach to the patient with immune checkpoint inhibitor-associated endocrine dysfunction. *J Clin Endocrinol Metab*. 2023;108(6):1514-1525. doi:10.1210/clinem/dgac689