trchealthcare

Pharmacotherapy of Acne

Updated November 2025

Acne should be managed with multimodal, combination therapy (including twice-daily use of a gentle cleanser).[1,2] Combination formulations may help improve adherence.[1]

Drug/Class	Place in Therapy	Comments
Retinoids, topical • tretinoin • adapalene (1% is OTC in the US) • tazarotene • trifarotene	• Cornerstone of acne treatment.[1] • Monotherapy or combined with other topicals for mild acne.[1] • Combine with other topicals and/or oral therapies for moderate to severe acne.[1]	• Use may be limited by dryness, burning, stinging, and scaling.[1] Improve tolerability with reduced frequency of use and moisturizers (with sunscreen).[1] • Efficacy and tolerability appear to differ by concentration and formulation (rather than by specific agent).[1] For example, micronized gels or polymerized cream formulations of tretinoin may be better tolerated. • Apply the non-microsphere formulation of tretinoin in the evening and NOT at the same time as benzoyl peroxide.[1] • Altreno and Atralin contain fish protein; use with caution in patients allergic to fish.[3]
Benzoyl peroxide, topical	• Monotherapy or combined with other topicals for mild acne.[1] • Combine with other topicals and/or oral therapies for moderate to severe acne.[1]	• Use may be limited by dryness, stinging, redness, and peeling.[1] • Start with lower concentrations, water-based or wash-off formulations, and reduced frequency to improve tolerability.[1] • May bleach hair and clothing.[1] • Do not apply at the same time as tretinoin (non-microsphere formulation).[1] • Benzoyl peroxide can potentially break down to form benzene (a carcinogen) under extreme heat.Store products as directed. Avoid exposure to heat (steam showers, car glove compartment, radiators). Can store in the refrigerator.[10]
Antibiotics, topical (e.g., clindamycin, erythromycin, minocycline [US], dapsone)	• Part of combination therapy for mild to severe acne.[1]	• Combine with other topical therapy to reduce the risk of antibiotic resistance and improve efficacy.[1] Avoid monotherapy.[1] • Oxidation can cause orange discoloration on the skin if dapsone is used with benzoyl peroxide.[1] Brush or wash discoloration off.[1]
Clascoterone, topical (Winlevi)	• Consider as an adjunct if other meds have failed for mild to severe acne.[1] • Combination therapy is recommended.[3] • Efficacy for both inflammatory and noninflammatory lesions.[4]	• Androgen receptor inhibitor, may help reduce oil production and inflammation.[3] • Indicated for patients 12 years and older.[3,5] • Adverse effects are mainly local (e.g., redness, dryness, edema, burning).[4,5] • Cases of hypothalamic-pituitary-adrenal (HPA) axis suppression have been reported. Avoid using over large areas, prolonged use, occlusive dressings.[4,5] • Refrigerate prior to dispensing. Patients may store at room temperature.[4,5]
Salicylic acid, topical	• Mild acne.[1] • May be part of combination therapy for moderate/severe acne.[1]	• Lower efficacy compared to benzoyl peroxide or tretinoin, but may be better tolerated.[6]
Azelaic acid, topical (Azelex [US], Finacea, generics)	• Option for mild to severe acne regimens, especially in patients with sensitive skin.[1] • As an adjunct for postinflammatory dyspigmentation (can help lighten the skin).[1]	• Appears to be comparable to adapalene and benzoyl peroxide when used as monotherapy.[7] • May be comparable in tolerability to adapalene and better tolerated than benzoyl peroxide.[7]
Antibiotics, oral (doxycycline, minocycline, sarecycline [US])	• Part of combination therapy for moderate to severe inflammatory acne.[1]	• Doxycycline is preferred.[1] • Combine with topicals (benzoyl peroxide or other topical) to reduce the risk of antibiotic resistance and improve efficacy.[1] Avoid monotherapy.[1] • Use for shortest duration possible (typically 3 to 4 months).[1] • Tetracyclines contraindicated during pregnancy and <9 years.[1]
Corticosteroids, intralesional	• Might show benefit with larger papules/nodules at risk of scarring and causing pain.[1]	• Data are limited.[1]
Cyproterone acetate/ ethinyl estradiol, oral (Canada only) (Diane-35, generics)	• Females with severe acne associated with androgenization and unresponsive to other treatments.[8]	• Antiandrogen/estrogen combination.[8] • Should not be prescribed for use as an oral contraceptive without acne indication (however, will provide reliable contraception when used for acne).[8] • Carries similar warnings and contraindications as other progestin/estrogen contraceptives, and a potential for an elevated risk of thromboembolism.[8]

Chart continued on next page...

Pharmacotherapy of Acne

Updated November 2025

Drug/Class	Place in Therapy	Comments
Isotretinoin, oral (e.g., Accutane, Absorica [US], Absorica LD [Canada], Claravis [US]) Ⓜ	• Patients with acne-related psychosocial burden and/or severe scarring.[1] • Treatment-refractory acne.[1]	• Commonly causes dry skin, lips, and eyes; nosebleeds; myalgias.[1] • Requires lipid and liver enzyme monitoring.[1] • **Rarely** associated with bone mineralization, inflammatory bowel disease, and mood changes (depression, anxiety, suicidal ideation).[1] • Formulations are NOT all interchangeable due to differences in absorption. • Check labelling for information on administering with food. • Isotretinoin is a well-established teratogen, therefore prescriber and patient must meet strict requirements of pregnancy prevention programs.[1]
Combination oral contraceptives ⊂⊃	• Females with moderate or severe acne.[1]	• May inhibit accrual of bone mass; avoid in patients under 14 years or 15 years (depending on formulation used).[1] • Efficacy not limited to products with labeled acne indication.
Spironolactone, oral ⊂⊃	• Moderate to severe acne, particularly in females with cyclic acne (i.e., flares around menstruation) or androgenization.[1,9]	• Dose range is 25 mg to 100 mg once or twice daily.[3] • Not FDA- or Health Canada-approved for acne. • Often combined with combined oral contraceptives to increase effectiveness.[9] • Consult labeling for important monitoring, cautions, and contraindications.
Hydrogen peroxide 1% cream, topical (Crystaderm, Canada only) Ⓜ ⊂⊃	• Option for mild to moderate acne, if benzoyl peroxide not tolerated.[11]	• Liquid hydrogen peroxide is **not** recommended for treatment of acne. • Promoted as a safer alternative to benzyl peroxide; however, data is lacking.

Icon Key

Ⓜ Monotherapy ⊂⊃ Combination Therapy Ⓜ AVOID Monotherapy

References

1. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2024 May;90(5):1006.e1-1006.e30.
2. Keow S, Xiong G, Abu-Hilal M. Update to acne vulgaris treatment for Canadian practice. Can Fam Physician. 2025 Jul-Aug;71(7-8):455-466. Erratum in: Can Fam Physician. 2025 Oct;71(10):612.
3. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. 2025. http://www.clinicalkey.com. (Accessed November 18, 2025).
4. Product information for Winlevi. Sun Pharmaceutical. Cranbury, NJ 08512. July 2022.
5. Product monograph for Winlevi. Sun Pharma Canada. Brampton, ON L6T 1C1. June 2023.
6. Dawson AL, Dellavalle RP. Acne vulgaris. BMJ. 2013 May 8;346:f2634.
7. Nast A, Dreno B, Bettoli V, et al. European evidence-based (S3) guideline for the treatment of acne - update 2016 - short version. J Eur Acad Dermatol Venereol. 2016 Aug;30(8):1261-8.
8. Product monograph for Diane-35. Bayer. Mississauga, ON L4W 5R6. February 2022.
9. American Academy of Dermatology Association. Stubborn acne? Hormonal therapy may help. https://www.aad.org/public/diseases/acne/derm-treat/hormonal-therapy#:~:text=Spironolactone:%20Doctors%20prescribe%20this%20medication,spironolactone%20can%20be%20quite%20effective.. (Accessed November 18, 2025).
10. American Acne & Rosacea Society. Response statement from the American Acne & Rosacea Society to the Valisure citizen petition on benzene in benzoyl peroxide drug products. https://acneandrosacea.org/uncategorized/american-acne-rosacea-society-aars-responds-to-citizen-petition-submitted-by-valisure-regarding-benzene-in-benzoyl-peroxide-drug-products/. (Accessed November 18, 2025).
11. Milani M, Bigardi A, Zavattarelli M. Efficacy and safety of stabilised hydrogen peroxide cream (Crystacide) in mild-to-moderate acne vulgaris: a randomised, controlled trial versus benzoyl peroxide gel. Curr Med Res Opin. 2003;19(2):135-8.

Drugs With Prescribing, Dispensing, or REMS Requirements

full update May 2026

Some prescription and over-the-counter (OTC) drugs have special requirements when they are dispensed, prescribed, or purchased. These requirements are usually intended to improve patient safety. Requirements mandated by FDA are called Risk Evaluation and Mitigation Strategies (REMS). Most REMS drugs also have a Medication Guide (MedGuides may also be available for medications that do not have a REMS). REMS may be as simple as dispensing a MedGuide. Most REMS are more involved, with components such as training courses for healthcare professionals and registries for patients (see **footnote b**). Some REMS apply to an entire drug class, such as with opioids. Besides REMS, there may be other special requirements mandated by federal law. For example, vaccine information statements (VIS) must be given to patients before administration of certain vaccines. Drugs used for relatively rare diseases may be available only through certain pharmacies, as with some treatments for pulmonary hypertension. The chart below summarizes requirements for select drugs. A complete list of REMS drugs along with details of each REM is available at www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

Drug/Drug Class Name	**Rationale for Requirements**	**Summary of Requirements** (also see **footnote b**)	**Contact Information**
Aficamten **Myqorzo**	Can cause heart failure due to systolic dysfunction.	• **Prescribers** of aficamten must certify in the Myqorzo REMS, counsel the patient about risks, provide the Patient Guide, and attest to electrocardiogram review. • **Patients** must complete the patient enrollment form with the prescriber and get electrocardiograms. • **Pharmacies** that dispense aficamten must certify in the Myqorzo REMS and obtain REMS authorization to dispense each prescription.	www.myqorzorems.com 844-285-7367
Alemtuzumab[a] **Lemtrada**	Can cause autoimmune conditions, infusion reactions, stroke, and malignancy.	• **Prescribers** of alemtuzumab must certify in the Lemtrada REMS, counsel patients on risks, give patients the Patient Guide and Patient Safety Information Card, and submit documentation of required monitoring. • **Patients** must complete the patient enrollment form with the prescriber, and be monitored for autoimmune conditions and malignancies during and for 48 months after the last infusion. • **Pharmacies** and **healthcare facilities** that dispense alemtuzumab must certify in the Lemtrada REMS and obtain REMS authorization to dispense each prescription.	www.lemtradarems.com 855-676-6326

Drug/Drug Class Name	**Rationale for Requirements**	**Summary of Requirements** (also see **footnote b**)	**Contact Information**
Alvimopan **Entereg** generics	Can increase the risk of heart attacks when used long-term.	• **Hospital pharmacies** must certify in the alvimopan REMS and verify that the patient received no more than 15 doses of alvimopan. • Alvimopan should NOT be dispensed to outpatients.	www.alvimopanrems.com 800-278-0340
Belantamab[a] **Blenrep**	Can cause ocular toxicity.	• **Prescribers** of belantamab must certify in the Blenrep REMS, educate patients about ocular toxicity, and submit documentation of required ophthalmic exams. • **Patients** must complete the patient enrollment form with the prescriber and get eye exams. • **Healthcare settings** that dispense belantamab must certify in the Blenrep REMS. The REMS must be contacted for authorization to dispense each dose.	www.blenreprems.com 855-690-9572
Bosentan[a] **Tracleer** generics	Can cause liver toxicity.	• **Prescribers** of bosentan must certify in the bosentan REMs, educate patients about liver toxicity, and assess liver function monthly. • **Patients** must complete the patient enrollment form with the prescriber and get liver tests. • **Pharmacies** (inpatient and outpatient) that dispense bosentan must certify in the bosentan REMS. o **Inpatient** pharmacies must verify prescriber, patient, and outpatient pharmacy REMS certification, counseling, and liver testing, and dispense no more than a 15-day supply. o **Outpatient pharmacies** must confirm liver testing, counsel on liver toxicity if not documented. The REMS must be contacted for authorization to dispense each prescription (limit: 30-day supply).	www.bosentanremsprogram.com 866-359-2612
Brodalumab[a] **Siliq**	Associated with an increased risk of suicidal thoughts and behaviors, and suicides.	• **Prescribers** of brodalumab must certify in the Siliq REMS program, counsel the patient about risks, and provide the Patient Wallet Card.	www.siliqrems.com 855-511-6135

Drug/Drug Class Name	**Rationale for Requirements**	**Summary of Requirements** (also see **footnote b**)	**Contact Information**
		• **Patients** must complete the enrollment form with the prescriber and carry the Patient Wallet Card at all times. • **Pharmacies** must certify in the Siliq REMS, and contact the REMS for authorization to dispense each prescription.	
Buprenorphine-containing transmucosal products for opioid dependence (BTOD)[a] **Zubsolv** **Suboxone** generics buprenorphine sublingual tablet	BTODs indicated for the treatment of opioid dependence pose risks of accidental overdose, misuse, and abuse. (REMS program does not apply to use of BTOD dispensed to patients admitted to an Opioid Treatment Program (OTP); these programs have their own requirements.)	• **Prescribers** must verify appropriateness and efficacy; counsel patient on risks, adherence, and safe storage, and complete and retain the REMS Appropriate Use Checklist.	www.btodrems.com 855-223-3922
Buprenorphine extended-release subcutaneous injection[a] **Sublocade**	Buprenorphine ER forms a solid mass when in contact with body fluids. Intravenous injection can cause serious harm or death.	• **Pharmacies** and **healthcare settings** must be certified to order and dispense Sublocade. o **Sublocade** can NOT be dispensed directly to the patient. • **Prescribers** who purchase Sublocade directly from a distributor must practice in a healthcare setting which is certified to dispense Sublocade.	www.sublocaderems.com 877-782-6966
Buprenorphine extended-release subcutaneous injection[a] **Brixadi**	Can cause serious harm or death if injected intravenously.	• **Pharmacists** and **healthcare settings** must be certified to order and dispense Brixadi. o Brixadi can NOT be dispensed directly to the patient. • **Prescribers** who purchase Brixadi directly from a distributor must practice in a healthcare setting which is certified to dispense Brixadi.	www.brixadirems.com 866-492-9624
Cisapride[a] **Propulsid**	Cisapride was withdrawn from the market because it can cause fatal arrhythmias.	• Available only through a limited access program for specific conditions (e.g., feeding intolerance in neonates). • Patients must meet clearly defined eligibility criteria for enrollment.	www.propulsid-lap.com 877-795-4247

Drug/Drug Class Name	Rationale for Requirements	Summary of Requirements (also see **footnote b**)	Contact Information
Collagenase clostridium histolyticum[a] **Xiaflex**	Can cause penile injury.	• **Prescribers** of collagenase clostridium histolyticum must certify in the Xiaflex REMS program. counsel the patient about risks, and provide the Patient Guide. • **Healthcare settings** and **pharmacies** that dispense collagenase clostridium histolyticum must certify in the Xiaflex REMS program and verify prescriber certification.	www.xiaflexrems.com 877-313-1235
Crovalimab-akkz **Piasky**	See eculizumab, below.		
Danicopan **Voydeya**	Has potential to increase the risk of serious infections caused by *Streptococcus pneumoniae* and *Neisseria meningitidis* types A, C, W, Y, and B.	• **Prescribers** of danicopan must certify in the Voydeya REMS, counsel the patient on risks, give patients the Patient Guide and Patient Safety Card, and bring patients up-to-date on meningococcal and pneumococcal vaccines at least two weeks prior to treatment initiation. If treatment is urgent, provide patient with a prescription for antibacterial drug prophylaxis. • **Pharmacies** (inpatient and outpatient) that dispense danicopan must certify in the Voydeya REMS. o **Inpatient pharmacists** must assess patient vaccination status/antibacterial prophylaxis and obtain REMS authorization to dispense each prescription. o **Outpatient pharmacies** must assess patient vaccination status/antibacterial prophylaxis before the first dose (and for up to 6 months afterward if initially unvaccinated), and obtain REMS authorization to dispense each prescription.	www.voydeyarems.com 888-765-4747
Denosumab[a] **Prolia** biosimilars (see footnote d)	Can cause severe hypocalcemia in patients with advanced kidney disease.	• **Healthcare providers** should counsel patients on risks and give patients the Patient Guide.	www.proliahcp.com/risk-evaluation-mitigation-strategy 800-772-6436 See **footnote d** for denosumab biosimilars.

Drug/Drug Class Name	**Rationale for Requirements**	**Summary of Requirements** (also see **footnote b**)	**Contact Information**
Duvelisib[a] **Copiktra**	Can cause serious or fatal infections, diarrhea, colitis, skin reactions, and pneumonitis.	• **Healthcare providers** should counsel patients on risks and give patients the Patient Safety Wallet card. • **Patients** should be counseled on risks and given the Patient Safety Wallet Card.	www.copiktrarems.com
Crovalimab-akkz **Piasky** Eculizumab[a] **Soliris** Eculizumab-aagh[a] **Epysqli** Eculizumab-aeeb[a] **BKEMV** Ravulizumab-cwvz[a] **Ultomiris**	Can increase the risk of meningococcal infections.	• **Prescribers** of crovalimab-akkz, eculizumab, eculizumab-aagh, eculizumab-aeeb, or ravulizumab-cwvz must certify in the corresponding REMS, give patients the Patient Guide and Patient Safety Card, and bring patients up-to-date on meningococcal vaccines at least two weeks prior to treatment initiation. If treatment is urgent, provide patient with a prescription for antibacterial drug prophylaxis. • **Pharmacies** (inpatient and outpatient) that dispense crovalimab-akkz, eculizumab, eculizumab-aagh, eculizumab-aeeb, or ravulizumab-cwvz must certify in the corresponding REMS. The REMS must be contacted for authorization to dispense each prescription. Pharmacies must assess patient vaccination status/antibacterial prophylaxis before the first dose and for up to 6 months afterward, if initially unvaccinated.	www.piaskyrems.com 888-835-2555 www.epysqlirems.com/s/hcs 866-318-0342 www.bkemvrems.com 866-718-6827 www.ultsolrems.com 888-765-4747
Elranatamab-bcmm[a] **Elrexfio** *Continued…* Elranatamab-bcmm,[a] continued	Can cause cytokine release syndrome (CRS) and neurologic toxicity.	• **Prescribers** of elranatamab-bcmm must certify in the Elrexfio REMS, counsel patients on risks and self-monitoring, and give patients the Patient Wallet Card. • **Healthcare settings** and **pharmacies** that dispense elranatamab-bcmm must certify in the Elrexfio REMS, and contact the REMS for authorization to dispense each prescription. • **Patients** should carry the Patient Wallet Card at all times.	www.elrexfiorems.com 844-923-7845
Etonogestrel implant **Nexplanon**	Improper insertion and removal can cause complications.	• **Prescribers** who insert Nexplanon must certify in the Nexplanon REMS by submitting the Provider Knowledge	

Drug/Drug Class Name	Rationale for Requirements	Summary of Requirements (also see **footnote b**)	Contact Information
		Assessment, completing in-person training, and submitting the Healthcare Provider Enrollment Form. • **Pharmacies** that dispense Nexplanon must certify in the Nexplanon REMS and dispense only to certified prescribers.	
Esketamine[a] **Spravato**	Can cause sedation, dissociation, and respiratory depression.	• **Healthcare settings** where Spravato is administered must certify in the Spravato REMS. Patients must be monitored for sedation, dissociation, and respiratory depression during and for at least two hours after administration. • **Patients** must complete the patient enrollment form with the prescriber. • **Pharmacies** that dispense Spravato must certify in the Spravato REMS. Spravato can only be dispensed to a certified healthcare setting; it can NOT be dispensed directly to the patient.	www.spravatorems.com 855-382-6022
Fenfluramine hydrochloride[a] **Fintepla** *Continued…* Fenfluramine, continued	Can cause valvular heart disease and pulmonary arterial hypertension.	• **Prescribers** of fenfluramine hydrochloride must certify in the Fintepla REMS. o Must submit a patient's echocardiogram results to the REMS prior to treatment, every 6 months during treatment, and 3 to 6 months after treatment discontinuation. • **Patients** must complete the patient enrollment form with the prescriber and get echocardiograms. • **Pharmacies** (inpatient and outpatient) that dispense fenfluramine hydrochloride must certify in the Fintepla REMS, and contact the REMS for authorization to dispense each prescription. Inpatient pharmacies cannot dispense more than a 15-day supply at discharge.	www.finteplarems.com 877-964-3649
Intrauterine device, copper **Miudella**	Insertion method is unique. Improper	• **Prescribers** must review the training program and be certified in the Miudella REMS.	www.miudellarems.com 855-337-0772

Drug/Drug Class Name	Rationale for Requirements	Summary of Requirements (also see **footnote b**)	Contact Information
	insertion can cause complications.	• **Pharmacies** and **healthcare settings** that dispense Miudella must certify in the Miudella REMS.	
Iptacopan[a] **Fabhalta**	Has potential to increase the risk of infections caused by *Streptococcus pneumoniae* and *Neisseria meningitidis* types A, C, W, Y, and B.	• **Prescribers** of pegcetacoplan must certify in the Fabhalta REMS, counsel the patient on risks, give patients the Patient Guide and Patient Safety Card, and bring patients up-to-date on meningococcal and pneumococcal vaccines at least two weeks prior to treatment initiation. If treatment is urgent, provide patient with a prescription for antibacterial drug prophylaxis. • **Pharmacies** (inpatient and outpatient) that dispense pegcetacoplan must certify in the Fabhalta REMS. o **Inpatient pharmacists** must assess patient vaccination status/antibacterial prophylaxis and obtain REMS authorization to dispense each prescription. o **Outpatient pharmacies** must assess patient vaccination status/antibacterial prophylaxis before the first dose (and for up to 6 months afterward if initially unvaccinated), and obtain REMS authorization to dispense each prescription.	https://fabhalta-rems.com/#Main 833-993-2242
Isotretinoin[a] **Absorica** **Absorica LD** **Amnesteem** **Claravis** **Myorisan** **Zenatane** generics	Isotretinoin is teratogenic.	• **Prescribers** of isotretinoin must certify in the iPLEDGE program, assess pregnancy status, and document counseling (monthly for patients who can get pregnant). • **Patients** must enroll in the iPLEDGE program. Patients who can get pregnant must follow REMS requirements for contraception and pregnancy testing (medical, then at home, if prescriber-approved),[c] and complete a monthly questionnaire. Pregnancy test must be repeated if the prescription is not picked up within seven days.	www.ipledgeprogram.com 866-495-0654

Drug/Drug Class Name	Rationale for Requirements	Summary of Requirements (also see **footnote b**)	Contact Information
		• **Pharmacies** must certify in the iPLEDGE program, obtain REMS authorization to dispense each prescription, and complete yearly training.	
Lenalidomide[a] **Revlimid** generics	Lenalidomide is teratogenic.	• **Prescribers** of lenalidomide must certify in the lenalidomide REMS; counsel patients on risks, safe storage, and disposal; provide the Patient Guide and Emergency Contraception Brochure; and follow REMS requirements for pregnancy testing.[c] • **Patients** must enroll in the lenalidomide REMS, follow REMS requirements for pregnancy prevention and complete a monthly questionnaire. • **Pharmacies** that dispense lenalidomide must certify in the Revlimid REMS. Pharmacists must obtain a confirmation number for each prescription and complete the Education and Counseling Checklist for Pharmacies.	www.lenalidomiderems.com 888-423-5436
Linvoseltamab-gcpt[a] **Lynozyfic**	Can cause cytokine release syndrome (CRS) and neurologic toxicity.	• **Prescribers** of linvoseltamab-gcpt must certify in the Lynozyfic REMS, counsel patients on risks and self-monitoring, and give patients the Patient Wallet Card. • **Healthcare settings** and **pharmacies** that dispense linvoseltamab-gcpt must certify in the REMS, and contact the REMS for authorization to dispense each prescription.	https://lynozyficrems.com/#Main 855-212-6391
Lomitapide[a] **Juxtapid**	Can cause liver toxicity.	• **Prescribers** of lomitapide must certify in the Juxtapid REMs, give patients the Patient Guide and discuss the information included, and complete required liver function monitoring. • **Patients** must complete the patient enrollment form with the prescriber and get liver tests. • **Pharmacies** that dispense lomitapide must certify in the Juxtapid REMS. For each prescription, pharmacies verify that the prescriber is certified, the Patient-Prescriber Acknowledgement form is on file, and the Prescription Authorization form is complete.	www.juxtapid.com/rems/ 855-898-2743

Drug/Drug Class Name	**Rationale for Requirements**	**Summary of Requirements** (also see **footnote b**)	**Contact Information**
Loxapine inhalation powder[a] **Adasuve**	Can cause bronchospasm leading to respiratory distress.	• **Healthcare facilities** must be certified in the Adasuve REMS to dispense loxapine inhalation powder and assess for breathing problems before and after administration.	www.adasuverems.com 855-755-0492
Mavacamten[a] **Camzyos**	Can cause systolic dysfunction and drug interactions.	• **Prescribers** of mavacamten must certify in the Camzyos REMS, counsel the patient about risks, provide the Patient Brochure, attest to electrocardiogram review, and screen for drug interactions. • **Patients** must be complete the patient enrollment form with the prescriber and get echocardiograms. • **Pharmacies** that dispense mavacamten must certify in the Camzyos REMS. Pharmacists complete a Drug Interaction and Counseling Checklist and obtain REMS authorization to dispense each prescription.	www.camzyosrems.com 833-628-7367
Melphalan **Hepzato Kit**	Can cause hemorrhage, liver toxicity, and thromboembolism.	• **Healthcare settings** must be certified in the Hepzato Kit REMS to dispense Hepzato Kit.	www.hepzatokitrems.com 833-632-0457
Methadone 40 mg dispersible tablets for oral suspension[a] See "Opioids" for info on the REMS for opioids for **pain**.	Methadone 40 mg is indicated for detox and maintenance treatment of opioid-addicted patients. It's not FDA-approved for pain.	• Methadone 40 mg is only available to authorized hospitals and facilities for detoxification and maintenance treatment of patients with opioid addiction. • Federal law does not restrict the use of methadone for the treatment of pain. Methadone 5 mg and 10 mg formulations are available for the treatment of pain.	Hikma 800-631-2174
Metreleptin[a] **Myalept**	Can cause side effects related to development of anti-leptin antibodies (e.g., hyperglycemia,	• **Prescribers** of metreleptin must certify in the Myalept REMS. • **Pharmacies** that dispense metreleptin must certify in the Myalept REMS. For each prescription, pharmacies verify	www.myaleptrems.com 855-669-2537

Drug/Drug Class Name	**Rationale for Requirements**	**Summary of Requirements** (also see **footnote b**)	**Contact Information**
	infections), and lymphoma.	that the prescriber is certified and has completed a Prescription Authorization Form.	
Mifepristone[a] **Mifeprex** generics	Can cause serious and sometimes fatal infections and bleeding.	• **Prescribers** of mifepristone must certify in the mifepristone REMS. A Prescriber Agreement Form must be submitted to the certified pharmacy. • **Patients** must sign the Patient Agreement Form. • **Pharmacies** that dispense mifepristone must certify in the mifepristone REMS program. (Healthcare settings where mifepristone will be dispensed by or under supervision of a REMS-certified certified prescriber do not require pharmacy certification.) For each prescription, pharmacies verify that the prescriber is certified. Prescription must be delivered to the patient within four days, unless approved by prescriber.	www.earlyoptionpill.com 877-432-7596
Mitapivat[a] **Aqvesme** *Continued…* Mitapivat, continued	Can cause liver toxicity.	• **Prescribers** of mitapivat must certify in the Aqvesme REMS, educate patients about liver toxicity, submit documentation of required liver function monitoring, and report any liver toxicity. • **Patients** must complete the patient enrollment form with the prescriber and get liver tests. • **Pharmacies** that dispense mitapivat must certify in the REMS, and contact the REMS for authorization to dispense each prescription (28-day limit).	www.aqvesmerems.com 877-772-4467
Mycophenolate[a] **CellCept** **Myfortic** **Myhibbin** generics	Associated with increased risk of pregnancy loss and congenital malformations.	• **Prescribers** of mycophenolate must submit the completed Prescriber Training Confirmation Form to the Mycophenolate REMS, counsel patients on risks and alternatives, provide the Patient Information Brochure to patients who can get pregnant, and follow pregnancy testing recommendations.	www.mycophenolaterems.com/#Main

Drug/Drug Class Name	**Rationale for Requirements**	**Summary of Requirements** (also see **footnote b**)	**Contact Information**
Natalizumab[a] **Tysabri** Natalizumab-sztn **Tyruko**	Can cause progressive multifocal leukoencephalopathy (PML), a rare viral brain infection.	• **Prescribers** must certify in the REMS and perform monitoring during and for 6 months after treatment. • **Infusion centers** that administer natalizumab must certify in the REMS, submit the Pre-infusion Patient Checklist, and administer natalizumab only to enrolled patients. • **Patients** must complete the patient enrollment form with the prescriber. • **Pharmacies** that dispense natalizumab must certify in the REMS and dispense natalizumab only to authorized infusion sites.	www.touchprogram.com 800-456-2255 https://tyruko-rems.com/#Main/!Main/Home 855-489-7856
Nicotine replacement therapy (e.g., NicoDerm CQ, NicoDerm)	FDA-approved for only for patients ≥18 years of age	• Patients <18 years of age need a prescription for nicotine replacement therapy.	None
Olanzapine extended-release injection[a] **Zyprexa Relprevv** *Continued…* Olanzapine extended-release injection, continued	Can cause post-injection delirium/sedation syndrome (PDSS).	• **Prescribers** of extended-release olanzapine injection must certify in the Zyprexa Relprevv REMS. • **Patients** must enroll in the Zyprexa Relprevv REMS. o Patients agree to be observed in the clinic for three hours after each injection, to have someone accompany them to their destination when they leave the clinic, and to avoid driving for the rest of the day. • **Pharmacies** must certify in the Zyprexa Relprevv REMS and obtain REMS authorization to dispense each prescription . Olanzapine extended-release injection must NOT be dispensed directly to the patient.	zyprexarelprevvprogram.com 877-772-9390
Opioid analgesics (oral opioids, intranasal butorphanol, transdermal fentanyl, buprenorphine for **pain**, methadone for **pain**)[a]	Potential for misuse, abuse, addiction, overdose, and death.	• All **healthcare professionals** involved in pain management (prescribers, pharmacists, nurses) are strongly encouraged to: o complete an accredited, REMS-compliant continuing education activity.	www.opioidanalgesicrems.com 800-503-0784

Drug/Drug Class Name	Rationale for Requirements	Summary of Requirements (also see **footnote b**)	Contact Information
		○ review opioid safe use, risks, storage, and disposal with patients at the time of prescription, and provide the Patient Guide. ○ advise that patients read the MedGuide. ○ consider use of risk assessment tools and patient/prescriber agreements.	
Parathyroid hormone[a] **Natpara**	Potential to cause osteosarcoma.	• **Prescribers** of parathyroid hormone must complete a training module and certify in the Natpara REMS. Prescribers must counsel **patients** on the risks of parathyroid hormone and submit the prescription and Patient-Prescriber Acknowledgement form to the Natpara REMS program. • **Pharmacies** that dispense parathyroid hormone must certify in the Natpara REMS. Pharmacies receive the prescription from the Natpara REMS, verify that the prescriber is certified, verify that the Patient-Prescriber Acknowledgement form is on file, and contact the patient to arrange shipment.	www.natpararems.com 855-628-7272
Peanut (*Arachis hypogaea*) allergen powder-dnfp **Palforzia**	Can cause anaphylaxis.	• **Healthcare settings** where peanut allergen powder-dnfp is administered must certify in the Palforzia REMS. During administration, a healthcare professional must be present to monitor for and manage anaphylaxis. A certified prescriber must be on-site. • **Prescribers** who treat patients with peanut allergen powder-dnfp must certify in the Palforzia REMS, counsel the patient about anaphylaxis, and prescribe epinephrine to keep on hand. • **Patients** must complete the patient enrollment form with the prescriber. • **Pharmacies** that dispense peanut allergen powder-dnfp must certify in the Palforzia REMS. Pharmacies verify	www.palforziarems.com 844-725-3679

Drug/Drug Class Name	Rationale for Requirements	Summary of Requirements (also see **footnote b**)	Contact Information
		that the prescriber is certified and the patient is enrolled. Pharmacies confirm that initial dose escalation is only dispensed to certified healthcare settings, and that only one dose level is dispensed to the patient at a time. Prior to shipping the daily dose pack to the patient, pharmacies must confirm that the patient tolerated the first dose of the dosing level in a monitored setting.	
Pegcetacoplan[a] **Empaveli**	Has the potential to increase the risk of infections caused by *Streptococcus pneumoniae*, and *Neisseria meningitidis* types A, C, W, Y, and B.	• **Prescribers** of pegcetacoplan must certify in the Empaveli REMS, counsel the patient on risks, give patients the Patient Guide and Patient Safety Card, and bring patients up-to-date on meningococcal and pneumococcal vaccines at least two weeks prior to treatment initiation. If treatment is urgent, provide patient with a prescription for antibacterial drug prophylaxis. • **Pharmacies** that dispense pegcetacoplan must certify in the Empaveli REMS, assess patient vaccination status/antibacterial prophylaxis before the first dose (and for up to 6 months afterward if initially unvaccinated), and obtain REMS authorization to dispense each prescription.	www.empavelirems.com 833-866-3346
Pegvaliase-pqpz[a] **Palynziq**	Can cause anaphylaxis.	• **Prescribers** and **pharmacies** that prescribe/dispense pegvaliase-pqpz must certify in the Palynziq REMS. o Prescribers counsel patients on anaphylaxis and prescribe an epinephrine auto-injector. • **Patients** must complete the patient enrollment form with the prescriber.	www.palynziqrems.com 855-758-7367
Pexidartinib[a] **Turalio**	Can cause liver toxicity.	• **Prescribers** of pexidartinib must certify in the REMS, provide the Patient Guide, and complete required liver function monitoring. • **Patients** must complete the patient enrollment form with the prescriber and get liver tests.	www.turaliorems.com 833-887-2546

Drug/Drug Class Name	**Rationale for Requirements**	**Summary of Requirements** (also see **footnote b**)	**Contact Information**
		• **Pharmacies** that dispense pexidartinib must certify in the REMS and obtain REMS authorization to dispense each prescription.	
Phentermine/ Topiramate extended-release capsules[a] **Qsymia** generics	Topiramate is teratogenic.	• **Pharmacies** that dispense phentermine/topiramate extended-release capsules must certify in the REMS program. A Medication Guide and Patient Brochure must be dispensed with each prescription.	www.phentoprems.com 800-269-6816
Pomalidomide[a] **Pomalyst** generics	Pomalidomide is teratogenic.	• **Prescribers** of pomalidomide must certify in the REMS program. • **Patients** must complete the patient enrollment form with the prescriber. Females who can get pregnant must follow REMS requirements for contraception and pregnancy testing,[c] and complete a monthly survey. Females who cannot get pregnant must complete a survey every 6 months. There are also requirements for males. • **Pharmacies** must certify in the REMS and obtain REMS authorization to dispense each prescription.	www.ps-pomalidomiderems.com/ 888-423-5436
Pseudoephedrine	Pseudoephedrine is regulated by the DEA because it is a methamphetamine precursor.	• Sellers must self-certify annually. • Must be kept behind the counter. • Patients must show identification and sign a logbook to purchase. • A maximum of 3.6 g/day and 9 g/month (30-day period) may be purchased from a retail pharmacy by an individual (7.5 g/30 days for mail-order customers). • If state laws are stricter than federal laws, state laws must be followed.	https://www.deadiversion.usdoj.gov/meth/combat-methamphetamine-epidemic-act.html
Quinine sulfate[a] **Qualaquin** generics	Has a "boxed warning" that risks of thrombocytopenia outweigh any potential benefit for leg cramps.	• Legal experts suggest the use of an informed consent form for prescribers to use when prescribing quinine off-label to treat leg cramps.	None

Drug/Drug Class Name	**Rationale for Requirements**	**Summary of Requirements** (also see **footnote b**)	**Contact Information**
Quizartinib[a] **Vanflyta**	Can increase risk of QT prolongation, Torsades de pointes, and sudden death.	• **Prescribers** of quizartinib must certify in the Vanflyta REMS, counsel patients on risks, and provide the Patient Wallet Card. • **Pharmacies** that dispense quizartinib must certify in the Vanflyta REMS program and verify prescriber certification for each prescription.	www.vanflytarems.com 855-212-6670
Ravulizumab-cwvz[a] **Ultomiris**	See Eculizumab, above.		
Riociguat[a] **Adempas**	Riociguat is teratogenic.	• **Prescribers** and **pharmacies** (inpatient and outpatient) that treat patients with or dispense riociguat must certify in the Adempas REMS. • **Patients** (female) must enroll in the Adempas REMS. Patients who can get pregnant must: o follow REMS requirements for contraception and pregnancy testing.[c]	www.adempasrems.com 855-423-3672
Sodium oxybate[a] **Lumryz** **Xyrem** generics **Xywav**	Has the potential for central nervous system and respiratory depression, misuse, abuse, diversion, and inappropriate prescribing.	• **Prescribers of sodium oxybate products** must certify in corresponding REMS program. • **Patients** must be complete the patient enrollment form with the prescriber. • Sodium oxybate products are available only through a certified specialty pharmacy, which ships the medication to the enrolled patient.	www.xywavxyremrems.com 866-997-3688 www.lumryzrems.com 877-453-1029 www.soxremsprogram.com 833-769-7367
Sparsentan[a] **Filspari**	Can cause liver toxicity.	• **Prescribers** of sparsentan must certify in the Filspari REMS, educate patients about liver toxicity, submit documentation of required liver function monitoring, and report any liver toxicity. • **Patients** must complete the patient enrollment form with the prescriber and get liver tests. • **Pharmacies** (inpatient and outpatient) that dispense sparsentan must certify in the Filspari REMS. For each prescription, pharmacies verify that the prescriber is	www.filsparirems.com/#Main www.filsparirems.com 833-513-1325

Drug/Drug Class Name	**Rationale for Requirements**	**Summary of Requirements** (also see **footnote b**)	**Contact Information**
		certified and the patient is enrolled. Pharmacists counsel patients on liver toxicity and verify testing is complete.	
Teclistamab-cqyv[a] **Tecvayli** Talquetamab-tgvs[a] **Talvey**	Can cause cytokine release syndrome (CRS), neurological toxicities.	• **Prescribers** must certify in the REMS program, counsel patients on risks, and provide the Patient Wallet Card. • **Pharmacies and healthcare settings** that dispense these drugs must certify in the REMS program and obtain REMS authorization to dispense each prescription.	www.tec-talrems.com 855-810-8064
Teduglutide[a] **Gattex**	Can cause gastrointestinal polyps and obstruction, and biliary and pancreatic disorders.	• **Prescribers** of teduglutide should complete training provided by the REMS.	www.gattexrems.com 855-542-8839
Testosterone undecanoate[a] **Aveed**	Can cause pulmonary oil microembolism and anaphylaxis.	• **Prescribers** of testosterone undecanoate must certify in the Aveed REMS. • **Healthcare settings** where testosterone undecanoate is administered must certify in the Aveed REMS. They must be able to treat pulmonary oil microembolism and anaphylaxis on-site.	www.aveedrems.com 855-755-0494
Thalidomide[a] **Thalomid**	Thalidomide is teratogenic.	• **Prescribers** of thalidomide must certify in the Thalomid REMS; counsel patients on risks; provide the Patient Guide and Emergency Contraception Brochure; and follow REMS requirements for pregnancy testing.[c] • **Patients** must enroll in the Thalomid REMS, follow REMS requirements for pregnancy prevention and complete a monthly survey. • **Pharmacies** that dispense thalidomide must certify in the Thalomid REMS. Pharmacists must obtain a confirmation number for each prescription and complete the Education and Counseling Checklist for Pharmacies.	www.thalomidrems.com 888-423-5436
Tolvaptan[a] **Jynarque** generics	Can cause liver toxicity.	• **Prescribers** of tolvaptan must certify in the REMS, counsel patent about risks, provide the Patient Guide, and complete required liver function monitoring.	https://tolvaptanadpkdsharedrems.ubc-training.com/#Main 866-244-9446

Drug/Drug Class Name	Rationale for Requirements	Summary of Requirements (also see **footnote b**)	Contact Information
		• **Patients** must complete the patient enrollment form with the prescriber. • **Pharmacies** (inpatient and outpatient) that dispense tolvaptan must certify in the REMS. Inpatient pharmacies can dispense not more than a 15-day supply. Outpatient pharmacies must obtain REMS authorization to dispense each prescription (limit: 30-day supply).	
Vigabatrin[a] **Sabril** generics *Continued…* Vigabatrin, continued	Can cause vision loss.	• **Prescribers** of vigabatrin must certify in the vigabatrin REMS program, counsel patient about risks, provide the Patient Guide, and complete required vision assessments. • **Patients** must complete the patient enrollment form with the prescriber. • **Pharmacies (inpatient and outpatient)** that dispense vigabatrin must certify in the vigabatrin REMS program. Pharmacies must obtain a confirmation number for each prescription. Inpatient pharmacies may not dispense more than a 15-day supply of vigabatrin upon discharge.	www.vigabatrinrems.com 866-244-8175
Zilucoplan[a] **Zilbrysq**	Increases the risk of meningococcal infection.	• **Prescribers** of zilucoplan must certify in the Zilbrysq REMS, give patients the Patient Guide and Patient Safety Card, and bring patients up-to-date on meningococcal vaccines at least two weeks prior to treatment initiation. If treatment is urgent, provide patient with a prescription for antibacterial drug prophylaxis. • **Pharmacies** that dispense zilucoplan must certify in the Zilbrysq REMS and verify prescriber certification for each prescription. Pharmacies must assess patient vaccination status/antibacterial prophylaxis before the first dose and for up to 6 months afterward, if initially unvaccinated.	www.zilbrysqrems.com 877-414-8353

a. Dispense a Medication Guide with each Rx.

b. **Examples of common REMS requirements.** In general, prescribers must complete an education or training activity (e.g., reading informational materials and passing a quiz) for REMS certification. Typically, the prescriber must agree to counsel the patient about medication risks and provide appropriate monitoring (e.g., liver function tests, pregnancy tests, complete blood count, cardiac monitoring). The REMS-certified prescriber is typically responsible for enrolling the patient in the REMS program. Patients may be required to agree to

drug-specific risk mitigation strategies such as use of reliable contraception (as defined by the REMS) or bloodwork. The prescriber might be required to complete a patient education checklist and/or provide the patient with certain educational materials. Requirements for pharmacy REMS certification often include completion of an education or training activity by a designated pharmacist. This pharmacist is then responsible for ensuring pharmacy adherence to REMS requirements. Pharmacies are typically required to verify prescriber REMS certification, patient enrollment, completion of required monitoring, and implementation of risk mitigation strategies before dispensing the drug. Prescriptions are typically limited to a 30-day supply. For some REMS, pharmacists might be required to provide certain patient education or screen for drug interactions.

c. **Contraception** and **pregnancy testing** requirements of REMS for teratogenic drugs vary. Contraception and pregnancy testing is typically required before, during, and after treatment. Instructions for pregnancy reporting are covered in the REMS.

d. **Denosumab biosimilars:** Bildyos **(**denosumab-nxxp[a]) https://www.bildyos-rems.com/; Boncresa (denosumab-mobz[a]) 877-835-5472**;** Bosaya (denosumab-kyqq[a]) www.bosayahcp.com/rems/; Conexxence (denosumab-bnht[a]) www.conexxencerems.com/; Enoby (denosumab-qbde[a]) https://www.enobyrems.com/; Jubbonti **(**denosumab-bbdz[a]) https://jubbontirems.com/; Ospomyv (denosumab-dssb[a]) www.ospomyvrems.com/; Osvyrti **(**denosumab-desu[a]) 866-941-7875; Ponlimsi (denosumab-adet) 888-483-8279; Stoboclo (denosumab-bmwo) www.stoboclorems.com

Users of this resource are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and internet links in this article were current as of the date of publication.

Cite this document as follows: **Clinical Resource*, Drugs with Prescribing, Dispensing, or REMS Requirements. Pharmacist's Letter/Pharmacy Technician's Letter/Prescriber Insights.* May 2026. [420561]**