A Resource on **REMS** for **Pharmacists**

BACKGROUND

The Risk Evaluation and Mitigation Strategies (REMS) program is a drug safety measure that pharmacists in many different settings will encounter and dispense. REMS are required by the U.S. Food and Drug Administration (FDA) to mitigate risks of adverse events and serious side effects from certain medications. The FDA requires particular activities or components to reinforce medication use behaviors because the agency has determined that risks of these medications may otherwise outweigh the benefits.[1] The potential components of the REMS may include dispensing a Medication Guide, a health care provider communication plan, Elements to Assure Safe Use (ETASU), and implementation systems. ETASU are medical interventions that range from patient assessments such as laboratory monitoring or vision assessments to certification requirements for the prescriber, pharmacy, or patient.[2]

The FDA determines whether a product requires a REMS program. The agency may seek input from stakeholders, health care providers, experts, and/or an FDA advisory committee. Drug manufacturers are responsible for developing and implementing the REMS; the FDA reviews the medication's REMS to ensure the agency's specifications are met and then approves the REMS. The FDA monitors the safety of the medication post-marketing and the REMS may be changed, added, or renounced completely.[3]

MANAGING REMS

REMS medications may come with an additional administration process, and it is important for pharmacists to know how to stay compliant with ETASU requirements. The pharmacy may be subject to an audit by the manufacturer, a third-party vendor on behalf of the manufacturer, or the FDA to assess the pharmacy's compliance with the REMS. Some of these programs require pharmacies or pharmacists to be certified to dispense a medication. Requirements for certification could include individual training of each pharmacist, or the manufacturer may require only one authorized individual to enroll the pharmacy and complete the training on behalf of the pharmacy. The authorized individual is expected to establish policies and procedures to ensure the pharmacy staff are compliant with the REMS requirements.[3] REMS certification requirements for individual drug products can be found on the FDA Approved REMS webpage.

Even if a hospital or other health system is not certified to dispense a REMS drug, there is always the possibility that a patient taking one of these products may be admitted into the facility. The best course of action for the health care facility to take would be to check the REMS database on the FDA website for more information on the requirements for the product to continue the patient on the medication. While many REMS medications are available through standard vendors, it is noteworthy that some REMS medications may need to be ordered through a special supplier.[3]

RECOGNIZING RESPONSIBILITY IN REMS

The pharmacist is the last checkpoint before patients receive their medications and therefore play an important role in ensuring patient safety. Pharmacists may accept prescriptions from all providers with prescribing privileges provided that they meet ETASU requirements set forth by the manufacturer. The pharmacist's responsibilities are to:

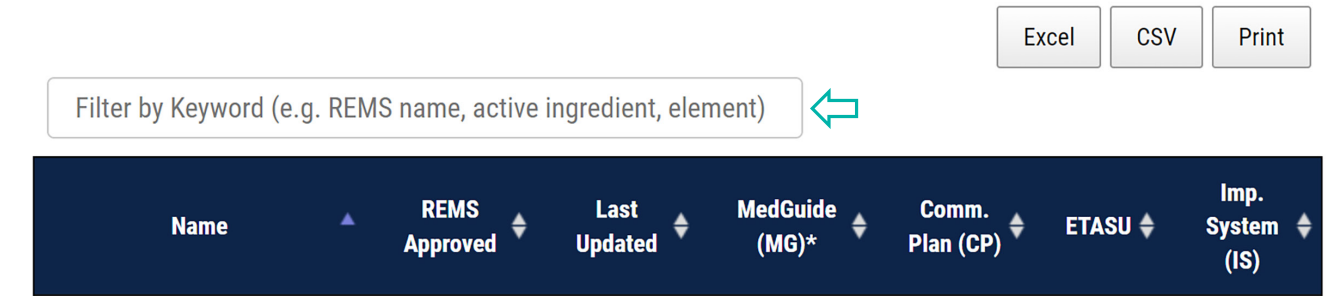
- Verify and document any labs or other monitoring requirements; this may also include physical examinations.*
- If required, verify the prescriber and patient's enrollment in the REMS program prior to dispensing.*
- Check any day supply limitations. Some REMS may require the patient to pick up the prescribed medication within a certain time window.
- Dispense any required Medication Guides and provide counseling for the patient.
- Stay up to date on any training that is required for the pharmacist and the pharmacy practice site.

* These requirements can be verified through the product's REMS website, by calling the manufacturer's REMS call center, or by using the pharmacy management system if it is built in. If the monitoring requirement(s) is not found through these channels, contact the prescriber to ensure it was completed.[3]

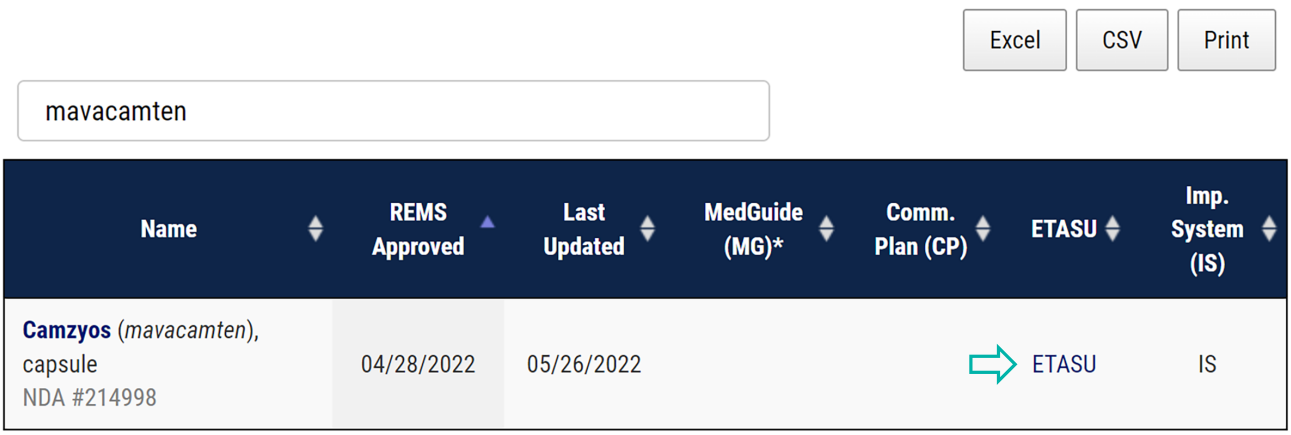
HOW TO FIND ETASU REQUIREMENTS FOR A REMS MEDICATION

1. Access the FDA's Approved Risk Evaluation and Mitigation Strategies (REMS)
2. Type the product name into the search bar

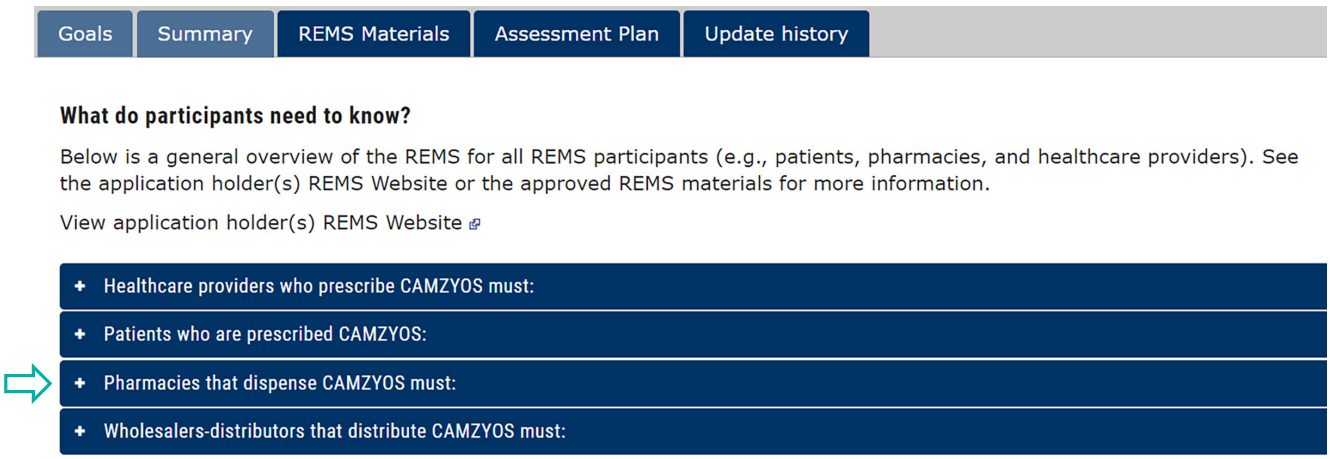
Information on historical and released REMS is available in downloadable: data files.



3. Click on "ETASU"



4. Click the + to expand the "Pharmacies that dispense" tab for more information on the product's REMS requirements



5. Review ETASU requirements

− Pharmacies that dispense CAMZYOS must:

To become certified to dispense	• Designate an authorized representative to complete the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. • Have the authorized representative review the Prescribing Information, the Education Program for Healthcare Providers and Pharmacies, and the Program Overview. | *REMS Program Overview* | | *Education Program for Healthcare Providers and Pharmacies* | • Have the authorized representative successfully complete the Pharmacy Authorized Representative Knowledge Assessment and submit it to the REMS. | *Pharmacy Authorized Representative Knowledge Assessment* | • Have the authorized representative enroll in the REMS on behalf of the pharmacy by completing the Pharmacy Enrollment Form and submitting it to the REMS. | *Pharmacy Enrollment Form* | • Train all relevant staff involved in dispensing CAMZYOS using the Program Overview and Education Program for Healthcare Providers and Pharmacies. | *REMS Program Overview* | | *Education Program for Healthcare Providers and Pharmacies* |
Before dispensing	• Counsel the patient on drug-drug interactions. • Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions. Document and submit to the REMS using the Drug Interaction and Counseling Checklist for Pharmacies. | *Drug Interaction and Counseling Checklist for Pharmacies* | • Document the prescribed dose. • Obtain authorization to dispense each prescription by contacting the REMS to verify that the prescriber is certified, the patient is enrolled, the healthcare provider has authorized the patient to receive the drug, the patient is counseled, and the pharmacy identified and resolved any drug-drug interactions. • Provide the patient with the Patient Brochure. | *Patient Brochure* | • Dispense no more than a 35-day supply of CAMZYOS.
To maintain certification to dispense	• Have the new authorized representative enroll in the REMS by successfully completing the Pharmacy Authorized Representative Knowledge Assessment and completing the Pharmacy Enrollment Form if the authorized representative changes. | *Pharmacy Authorized Representative Knowledge Assessment* | | *Pharmacy Enrollment Form* |
At all times	• Report adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb. • Do not distribute, transfer, loan, or sell CAMZYOS, except to a certified pharmacy. • Maintain records of dispensing information. • Maintain records of completion of the REMS training by relevant staff. • Maintain records that all processes and procedures are in place and are being followed. • Comply with audits conducted by MyoKardia, Inc. or a third party acting on behalf of MyoKardia, Inc. to ensure that all processes and procedures are in place and are being followed.

REMS RESOURCES

Questions/Concerns/Comments about REMS are welcome by the FDA by using the Contact REMS Form.

List of currently Approved REMS medications and their ETASU.

REFERENCES

1. Lippmann E. Risk Evaluation and Mitigation Strategies (REMS). Office of Regulatory Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration. Accessed August 30, 2022. https://www.fda.gov/media/105565/download
2. U.S. Food and Drug Administration. What's in a REMS? January 26, 2018. Accessed August 22, 2022. https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems
3. U.S. Food and Drug Administration. Roles of Different Participants in REMS. March 24, 2020. Accessed August 22, 2022. https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/roles-different-participants-rems

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