Oral Oncology Risk Evaluation & Mitigation Strategies (REMS)

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Background

- A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.
- REMS is designed to reinforce medication use behaviors and actions that support the safe use of that medication. While all medications have labeling that informs healthcare stakeholders about medication risks, only a few medications require a REMS

Discussion

- It is important for the healthcare provider to directly educate the patient when prescribing REMS medications
  - Utilizing NCODA's Oral Chemotherapy Education (OCE) Sheets
  - Manufacture specific education materials
- Healthcare providers play a central role in REMS implementation, with specialized training and certification requirements to ensure competency in managing patients receiving REMS products
- Ongoing monitoring and evaluation by healthcare providers are crucial for detecting and managing adverse events
- Before becoming certified, Pharmacy REMS education counselors obtain training through the manufacturer's website and/or online courses and continue to receive training on an ongoing basis. Access to REMS drugs can be challenging due to PMB dispensary location limitations and/or dispensing requirements.
- High Costs associated with REMS drugs can affect compliance for Medicare Part D patients.

Methods

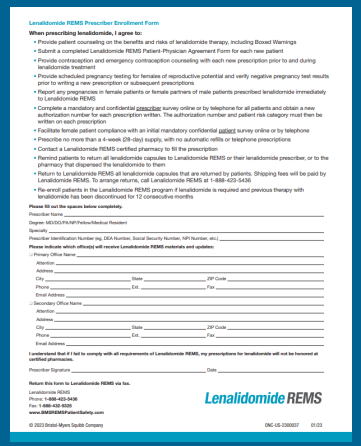
- Prescribing MD, DO, NP or PA must be enrolled as a provider in the REMS Program for each product they wish to prescribe
- Patients must complete REMS enrollment and sign consent to be on medication.
- An authorization number must be obtained by the provider from the REMS program to be written on the prescription
- The FDA orders Risk Evaluation & Mitigation Strategies (REMS) for certain drugs or biologics with significant toxicity levels and/or that demonstrate risk factors to assess adverse risks associated with certain specific oncologic drugs. These strategies are meant to ensure that the benefits of the drug continue to outweigh the risks it poses to patients.

Objective

- Three Common Components to a REMS Program
  1. Medication guide or patient package insert
  2. Communication plan for healthcare providers
  3. Elements To Assure Safe Use (ETASU)
- Specific drug REMS programs may include 1 or all 3 components based on the severity of the risks and the population likely to be exposed. The most common REMS only requires the provision of a medication guide to be given at each dispense

Oral Oncolytic REMS Products

- Duvelisib (Copiktra)- Communication plan
- Idelaisib (Zydelig)- Communication plan
- Lenalidomide (Revlimid)- ETASU, Implementation system
- Panobinostat (Farydak)- Communication plan
- Pomalidomide (Pomalyst)- ETASU, Implementation system
- Thalidomide (Thalomid)- ETASU, Implementation system
- Vandetanib (Caprelsa)- ETASU, Implementation system
- Pexdartinib (Turalio)- ETASU, Implementation system
- Quizartinib (Vanflyta)- ETASU, Implementation system
- Iptaoccan (Fabhalta)- ETASU, Implementation system


Lenalidomide REMS Prescriber Enrollment Form

When prescribing lenalidomide, I agree to:

- Provide patient counseling on the benefits and risks of lenalidomide therapy, including Boxed Warnings
- Submit a completed Lenalidomide REMS Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during lenalidomide treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed lenalidomide immediately to Lenalidomide REMS
- Complete a mandatory and confidential prescriber survey online or by telephone for all patients and obtain a new authorization number for each prescription written. The authorization number and patient risk category must then be written on each prescription
- Facilitate female patient compliance with an initial mandatory confidential patient survey online or by telephone
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact a Lenalidomide REMS certified pharmacy to fill the prescription
- Remind patients to return all lenalidomide capsules to Lenalidomide REMS or their lenalidomide prescriber, or to the pharmacy that dispensed the lenalidomide to them
- Return to Lenalidomide REMS all lenalidomide capsules that are returned by patients. Shipping fees will be paid by Lenalidomide REMS. To arrange returns, call Lenalidomide REMS at 1-888-423-5436
- Re-enroll patients in the Lenalidomide REMS program if lenalidomide is required and previous therapy with lenalidomide has been discontinued for 12 consecutive months

Please fill out the spaces below completely.

Prescriber Name

Degree: MD/DO/PA/NP/Fellow/Medical Resident

Specialty

Prescriber Identification Number (eg, DEA Number, Social Security Number, NPI Number, etc.)

Please indicate which office(s) will receive Lenalidomide REMS materials and updates:

– Primary Office Name

Attention

Address

City State ZIP Code

Phone Ext Fax

Email Address

– Secondary Office Name

Attention

Address

City State ZIP Code

Phone Ext Fax

Email Address

I understand that if I fail to comply with all requirements of Lenalidomide REMS, my prescriptions for lenalidomide will not be honored at certified pharmacies.

Prescriber Signature Date

Return this form to Lenalidomide REMS via fax.

Lenalidomide REMS

Phone: 1-888-423-5436

Fax: 1-888-423-5555

www.BMSREMSPatientSafety.com

Lenalidomide REMS

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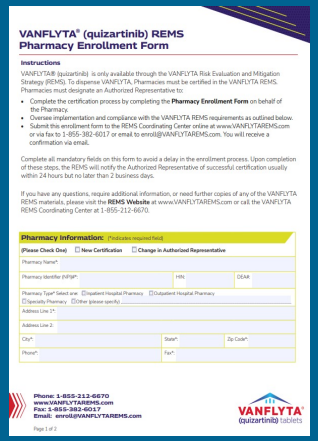
VANFLYTA® (quizartinib) REMS Pharmacy Enrollment Form

Instructions

VANFLYTA® (quizartinib) is only available through the VANFLYTA Risk Evaluation and Mitigation Strategy (REMS). To dispense VANFLYTA, Pharmacies must be certified in the VANFLYTA REMS. Pharmacies must designate an Authorized Representative to:

- Complete the certification process by completing the **Pharmacy Enrollment Form** on behalf of the Pharmacy.
- Oversee implementation and compliance with the VANFLYTA REMS requirements as outlined below.
- Submit this enrollment form to the REMS Coordinating Center online at www.VANFLYTAREMS.com or via fax to 1-855-382-6017 or email to enroll@VANFLYTAREMS.com. You will receive a confirmation via email.

Complete all mandatory fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify the Authorized Representative of successful certification usually within 24 hours but no later than 2 business days.

If you have any questions, require additional information, or need further copies of any of the VANFLYTA REMS materials, please visit the **REMS Website** at www.VANFLYTAREMS.com or call the VANFLYTA REMS Coordinating Center at 1-855-212-6670.

Pharmacy Information: (*Indicates required field)

(Please Check One) ☐ New Certification ☐ Change in Authorized Representative

Pharmacy Name*

Pharmacy Identifier (NPI)* HIN DEA#

Pharmacy Type* Select one: ☐ Inpatient Hospital Pharmacy ☐ Outpatient Hospital Pharmacy

☐ Specialty Pharmacy ☐ Other (please specify)

Address Line 1*

Address Line 2

City* State* Zip Code*

Phone* Fax*

Phone: 1-855-212-6670
www.VANFLYTAREMS.com
Fax: 1-855-382-6017
Email: enroll@VANFLYTAREMS.com

VANFLYTA® (quizartinib) tablets

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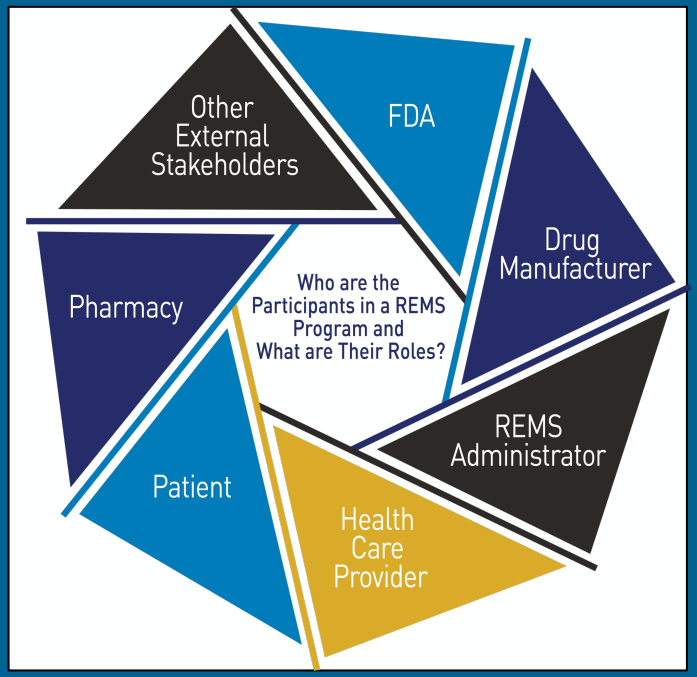
Conclusion

- The implementation of the REMS Program for oral oncolytics medications plays a crucial role in promoting patient safety and optimizing treatment outcomes.
- Patient education and counseling are fundamental components of REMS
- Healthcare provider training and certification ensure that clinicians are equipped with the knowledge and skills necessary to manage and monitor patients receiving oral oncolytic medications
- Collaboration between healthcare providers, pharmacists, pharmacy technicians, and patients I essential for successful REMS implantation, fostering a team-based approach to patient care
- The ability to prescribe and dispense REMS medications can be contingent upon compliance with the specific REMS Program
- The REMS Program for oral oncolytics promotes safe use in specific populations thus enhancing patient outcomes
- Overall, the various oral oncolytic REMS medications continue to improve patient care and play a critical role in oncology.



Research C for DE and. From Our Perspective | A Two-Part Series: Risk Evaluation and Mitigation Strategies (REMS) Program. *FDA*. Published online November 2, 2023. https://www.fda.gov/drugs/our-perspective/our-perspective-two-part-series-risk-evaluation-and-mitigation-strategies-rems-program