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 demonstrates risk factors to assess adverse events, 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
- Idelalisib (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
- Pexidartinib (Turalisio) - ETASU, Implementation system
- Quizartinib (V 것이나) - ETASU, Implementation system
- Ipatasertib (Fাবলতা) - ETASU, Implementation system

Conclusion

- The implementation of the REMS Program for oral oncolytic 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 is 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.