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REVIEW THE TRIALS SUPPORTING THE LATEST APPROVAL

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FORUMREWIND provides summaries of key sessions from NCODA's annual International Spring Forum written by members of Professional Student Organization chapters from around the world. To view slides from presentations, scan the OR code at the end of the summaries.

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Running Through Life with Purpose and Grace: A Survivor Helps Patients Thrive

PRESENTER: Dawn Mussallem, DO, DipABLM | Mayo Clinic

SYNOPSIS: Mussallem took an in-depth dive into living life to the fullest after being diagnosed with stage IV cancer followed by, heart failure. She explored the principles of lifestyle medicine, with an emphasis on the role of nutrition on patients' quality of life.

PRESENTATION: While in medical school, Mussallem collapsed due to cardiogenic shock and was diagnosed with stage 4 B-cell lymphoma. She was encouraged to drop out of medical school, but remained as it gave her purpose. After undergoing chemotherapy and radiation, she was cured of her cancer, completed school and started a family.

A few years later, she was again rushed to the emergency room. She again experienced cardiogenic shock, but this

time it was due to severe heart failure as a result of radiation. She was told doctors would do their best to manage her condition with treatment. She eventually received a heart transplant from an IV drug user and, as a result, contracted hepatitis C. To push herself to the limit one-year post-transplant, Mussallem ran a marathon.

As someone who was determined from a young age to live a very long life, she based her life and her patients' journeys on the six pillars of lifestyle medicine: healthful eating of whole, plant-based food, increasing physical activity, managing stress and maintaining relationships, improving sleep, and avoiding risky substances.

She stressed the importance of avoiding processed food, sugary drinks and alcohol. She also discussed the increased consumption of fiber through whole grains, vegetables, fruits and beans. Being physically active every day is key to a healthy life, as a sedentary life increases both

incidences of cancer and cancer death. The increase in exercise and decrease in processed foods also results in achieving and maintaining a healthy weight.

DISCUSSION:

Q: How much exercise should we recommend to our patients on active cancer treatment?

A: A 30-minute walk five to six days a week for 150 to 300 minutes a week of exercise

TAKEAWAY POINTS:

• The six pillars of lifestyle medicine have favorable results regarding disease management and reduced mortality.

Summary by **Lindsey Graham**, MBA, PharmDc (2024), Keck Graduate Institute.

SESSION SLIDES: Scan the QR code at right to view slides from this presentation.



Attacking Colorectal Cancer: Latest Updates for Treating Patients

PRESENTER: Arturo Loaiza-Bonilla, MD, MSEd, FACP | Capital Health

SYNOPSIS: Loaiza-Bonilla discussed new advancements in colorectal cancer (CRC). Implementation of sequencing technologies in practice can identify biomarkers that can individualize CRC therapy.

PRESENTATION: Treatment of CRC was previously based on tumor location, but there is a recent shift to using biomarkers through pharmacogenomic testing to guide therapy. Next-generation sequencing is an inexpensive tool to identify differences in genomic biomarkers in all cancers, not just colorectal cancer.

The DYNAMIC study discovered participants expressing circulating tumor deoxyribonucleic acid (ctDNA) had a higher rate of recurrence of CRC over participants negative for ctDNA and a low clinical risk. Loaiza-Bonilla detailed how a

ctDNA treatment guided approach can identify the subset of patients who would benefit from adjuvant chemotherapy following surgery.

The role of checkpoint inhibitors was discussed in the treatment of CRC through the use of dostarlimab. Dostarlimab is a monoclonal antibody that inhibits programmed cell death protein-1 (PD-1) receptors to prevent binding with its corresponding ligands. Participants with high microsatellite instability in locally advanced CRC were given dostarlimab, and all participants enrolled experienced no recurrence of CRC after treatment. Loaiza-Bonilla highlighted the introduction of a new mode of therapy, immunoablative therapy, to allow patients to achieve complete response without surgery.

The growing use of artificial intelligence (AI) and sequencing is a potential resource for providers to identify appropriate patient-specific treatments. AI can improve a patient's overall survival by optimizing treatment regimens depending on the ge-

netic alteration of a tumor. This can be used to improve cancer diagnoses and to receive real-time data updates all at a lower cost.

Loaiza-Bonilla presented clinical trial data to evaluate new advancements in the treatment of CRC. New methods of treatment, such as immunoablative therapy, sequencing and Al can improve outcomes in the quality of life and overall survival.

TAKEAWAY POINTS:

- Implementation of total neoadjuvant therapy is shown to improve outcomes in patients with CRC.
- Immunoablative therapy through the use of dostarlimab may enable some patients to have a complete response in treatment of CRC, without surgery.

Summary by **Jessica Samuel**, PharmDc (2024), University of Rhode Island.

SESSION SLIDES: Scan the QR code at right to view slides from this presentation.



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The Current & Future State of Medically Integrated Pharmacy Accreditation: Delivering Positive Patient-Centered Outcomes While Bringing Value to the MIP

PRESENTERS: Elizabeth Bell | NCODA; Annie Wingo, CPhT | Clearview Cancer Institute; Karrie McCowen, CPhT, RPhT | Rx To Go, LLC / Florida Cancer Specialists & Research Institute; Samuel Hernandez, LPhT | Southern Oncology Hematology Associates

SYNOPSIS: The session discussed positive outcomes and feedback from participating pharmacies in the NCODA Center of Excellence (CoE) Medically Integrated Pharmacy (MIP) Accreditation Program. Three MIPs shared their experiences, highlighting the program's benefits in improving patient care and outcomes.

PRESENTATION: The NCODA MIP accreditation program is compliant with

the ASCO/NCODA Patient-Centered Standards. It aims to enhance integrated patient care and quality of services provided by MIPs.

Clearview Cancer Institute has been successful in improving patient adherence and speed to therapy, as well as providing a more streamlined process, enhanced communication, and improved patient experiences.

Southern Oncology and Hematology Associates and Florida Cancer Specialists, have reported positive feedback and cost avoidance due to the program.

The accreditation training provides tools and resources for a smooth process, including a designated team lead and designated persons from each department.

DISCUSSION:

Q: How do you ensure that the oncology clinic is maintaining compliance with the standards for the prescriptions you are transferring out?

A: MIPs have dedicated team members,

work on dispensing, maintaining quality and transfer prescriptions to patients.

TAKEAWAY POINTS:

- The NCODA CoE MIP Accreditation Program is the first and only accreditation program for oncology MIPs, multispecialty MIPs and multispecialty MIPs with a significant oral oncology patient population. It eliminates clinical fragmentation and has patient-centered and innovation standards.
- The program provides dedicated ongoing support, accreditation tools, budget friendly and resources.
- MIPs that are accredited with NCODA provide quality of care by being patient-centered, innovative and collaborative.

Summary by **Yuthika Patel**, PharmDc (2025), South University.

SESSION SLIDES: Scan the QR code at right to view slides from this presentation.



KRASh Course in KRAS^{G12C} Inhibitors and Dose-Rounding Protocols

PRESENTERS: Kelly M. Brunk, PharmD, BCOP | The University of Kansas Health System; Alga S. Ramos Morales, PharmD, MS, MBA, BCPS, BCOP, CSSGB | Miami Cancer Institute | Baptist Health South Florida

SYNOPSIS: Brunk explained KRAS^{G12C} inhibitors including indications, dosing, monitoring, and adverse effects. Morales discussed the risks and benefits of dose rounding and current recommendations.

PRESENTATION: In lung cancer, KRASG12C is a common mutation leading to uncontrolled cell growth. Inhibitors bind covalently to GDP-bound KRAS irreversibly inactivating it. Sotorasib and adagrasib are the only currently U.S Food and Drug Administration-approved KRAS Inhibitors for locally advanced or metastatic KRASG^{12C} mutated non-small cell lung cancer patients who received at least one prior systemic therapy.

Sotorasib or LUMAKRAS™ is dosed once daily with or without food. Sotorasib has warnings of hepatotoxicity and pulmonary toxicity and main adverse effects include edema, rash, musculoskeletal pain, mild nausea, proteinuria, hypocalcemia, hyponatremia and hypoalbuminemia. Antiemetics may be considered as needed. Sotorasib has drug interactions with acid-reducing medications and P-qp, BCRP, or CYP3A4 substrates.

Adagrasib or KRAZATI™ is dosed twice daily with or without food. Adagrasib has warnings of hepatotoxicity, gastrointestinal bleeding, pulmonary toxicity and QT prolongation. The main adverse effects include edema, prolonged QTc, diarrhea, rash, musculoskeletal pain, elevated creatine phosphokinase (CPK), elevated serum creatinine (sCr), moderate nausea, hypomagnesemia, hypokalemia and hypoalbuminemia. Antiemetics are recommended as premedication prior to each dose. Adagrasib interacts with QT-prolonging medications and CYP2C9, CYP3A4, CYP2D6 and P-qp substrates.

Dose rounding decreases waste, reduce cost and potentially mitigates toxicities when rounding down. Benefits include increased patient adherence and minimized financial toxicity. Each institution should institute its own standardized protocols and exclusions. Dose rounding is especially useful in weight-based doses for oral or IV oncolytics. For oral chemotherapy, using a single-strength tablet is recommended to avoid confusion and financial issues.

TAKEAWAY POINTS:

- Two KRAS inhibitors are available with comparable efficacy but differing drug interactions and adverse effects.
- Dose rounding may benefit both patients and institutions..

Summary by **Adriana Hudson**, PharmDc (2024), University of Minnesota.

SESSION SLIDES: Scan QR codes to view slides from these presentations.





The Development of Immunotherapy and Immunology in Cancers & What Pharmacy Technicians Need to Know About Step Therapy

PRESENTERS: Sal Bottiglieri, PharmD, BCOP | Moffitt Cancer Center; Vonda McClendon, CPhT | Texas Oncology; Lindsey Scott, R.CPhT | Texas Oncology

SYNOPSIS: Bottiglieri discussed general classes and mechanism of action for contemporary immunotherapy in oncology practice. McClendon and Scott covered step therapy.

PRESENTATION: Bottiglieri discussed the immune system, including how both immune function and immune evasion work. Immunotherapy agents were discussed, including cytokine therapy, immune checkpoint inhibitors, adoptive cell therapy, oncolytic viruses, and cancer vaccines. He described the adverse

effects of immunotherapy, highlighting that they can be serious and require prompt diagnosis, treatment and patient education. Commonly occurring effects in checkpoint inhibitors include mild nausea, fatigue and myalgia.

McClendon and Scott explained that step therapy is a type of prior authorization for drugs that begins medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary. They discussed the challenges of step therapy rejections, which require specific documentation compared to traditional prior authorizations, and shift clinical decision-making away from the physicians.

DISCUSSION:

Q: For step therapy, is there a specific turnaround time for insurance companies to respond to coverage requests and supporting documentation?

A: No, there is not a turnaround time required by law. Some companies take weeks. They suggested sending supporting documentation early and maintaining frequent communication to mitigate delays.

TAKEAWAY POINTS:

- Immunotherapy agents have various adverse effects as compared with traditional chemotherapy. Having a good understanding of these effects is crucial in providing safe patient care.
- Step therapy is a type of prior authorization starting with the most preferred drug therapy and progressing to others only if necessary.

Summary by **Michelle Johnston**, PharmDc (2023), University of Cincinnati College of Pharmacy.

SESSION SLIDES:

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Empowering The Future Generation of Oncology Leaders

Our focus is to offer an international community for healthcare students with a passion in oncology and pharmaceutical industry. The NCODA Professional Student Organization (PSO) was established for students interested in oncology, association management, healthcare advocacy and policy, and industry leadership.



LOCATIONS OF ESTABLISHED PSO CHAPTERS





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Email Cooper Bailey at cooper.bailey@ncoda.org

Scan to visit, or check out www.ncoda.org/professional-student-organizations

Considerations When Caring for LGBTQIA+ Patients

PRESENTER: Maya Leiva, PharmD, BCOP, APh | Inova Schar Cancer Institute

SYNOPSIS: Leiva led a detailed discussion on the topic the of LGBTQIA+ community and their care. She highlighted the impact on members of the LGBTQIA+ community of often being misunderstood and their unwillingness to seek out healthcare. She also discussed importance of healthcare workers being properly educated to provide an equal level of healthcare to the LGBTQIA+ community.

PRESENTATION: Leiva discussed the negative effects of health disparities on the LGBTQIA+ community. She briefly defined "the Gender bread person," which includes identity, expression, biological sex, and sexual orientation. She emphasized that providers should never assume a patient's pronoun. Using correct pronouns creates a safe space for patients and colleagues. The health disparities that

occur at higher rates are for this population include human immunodeficiency virus, other sexual transmitted diseases and eating disorders. Increased rate of prostate, breast, testicular cancer occur due to hesitation of seeking healthcare, resulting in late screening.

Many barriers to care arise, such as clinics not requiring cultural competency training, lack of standardized methods to collect sexual orientation and gender identity data, and lack of culturally sensitive screening.

"As healthcare providers, it is our duty to change the narrative," Leiva noted. "We can do our part through avoiding discrimination by embracing a person's identity, reducing the rate of harm by validating and emphasizing the patient's feelings and values, and acknowledging clinical blind spots by treating every patient ethically."

DISCUSSION:

Q: What do you think would be a good way to integrate LGBTQIA+ education in

the pharmacy school curriculum?

A: Leiva emphasized not putting the LGBTQIA+ community into a special population category. Schools probably will not require knowledge of LGBTQIA+ care to be taught unless the board mandates their recognition as equal importance.

Q: What can medical professionals do to be more inclusive of the LGBTQIA+ community?

A: Leiva suggested putting up signs, wearing pins, increasing pronoun use in clinic and participating in health equality indexes.

TAKEAWAY POINTS:

• Improving healthcare quality and access for patients requires trauma-informed care and active efforts to decrease barriers for LGBTQIA+ patients.

Summary by **Shivani Patel**, PharmDc (2024), Auburn University.

SESSION SLIDES: Scan the QR code at right to view slides from this presentation.



Oral Anticancer Medication (OAM) Monitoring Workshop

MODERATOR: Mary K. Anderson, BSN, RN, OCN | NCODA

PRESENTERS: Suzanne Hinman RN, OCN | Smilow Care Center-Yale New Haven; Dallas Lawry, DNP, FNP-C, OCN | University of California

SYNOPSIS: Panelists elaborated on the significance and need for implementation of nursing-specific therapeutic strategies and workflows in the monitoring of Oral Anticancer Medications (OAMs).

PRESENTATION: U.S. Food and Drug Administration-approved OAMs are useful in improving clinical outcomes of various cancer types, but are associated with potential toxicities. Continual assessment and monitoring are vital clinical management practices for patients taking these medications. Currently, the underdevelopment of metrics in oral anticancer therapy monitoring are proven contributors to patients falling through cracks in the cancer care

system. This has led to the recommendation of an oncology-specific nursing role to help expand the scope of drug specific assessments and further develop monitoring workflows in OAM management.

The deployment of this role along with an efficient protocol will allow patients to be managed and triaged at the nursing level. This is essential as adhering to regimens, attending scheduled laboratory appointments, reporting adverse side effects, and attending provider follow-up visits are key elements in proactive workflows for OAM monitoring. To support this, it was recommended that the use of interprofessional collaboration in maintaining electronic medical records be used to yield positive outcomes and health services for populations undergoing OAM treatment.

As of now, the OAM nursing role has yet to be fully integrated into oncology care. However, the demand in workflow utilization, efficient monitoring and improvement in patient care discussed may justify the need for the dedicated role.

DISCUSSION:

Q: How does the oncology nurse provide value to the practice by tracking oral anticancer medication?

A: The OAM nursing role provides patient support through education, ongoing assessment, and continued communication that advocate for both the patient and their caregivers throughout their treatment

TAKEAWAY POINTS:

• There is a lack of existing standardized protocols and proactive workflows for nurses to appropriately monitor OAMs, which leads to nonadherence and toxicities.

Summary by **JD Fontenot**, PharmDc (2025), Texas Southern University.

SESSION SLIDES: Scan the QR code at right to view slides from this presentation.



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Value-Based Care: Looking into the Future

PRESENTER: Maggie Black, BSN, RN, OCN | Cancer Specialists of North Florida

SYNOPSIS: Black gave a presentation on the benefits of value-based care. She described the advantages value-based care and the oncology care model (OCM) have over the current model of fee-for-service care. Black explained the components, requirements, and benefits of value-based care and future payer models before opening a discussion on the implementation of these practices.

PRESENTATION: Black began by defining value-based care. Value-based care focuses on giving high value services to patients, rather than the current fee-for-service model, which can place an emphasis on volume over value. The OCM works to enhance quality of care while cutting costs by implementing quality-based payments in patients on Medicare Part B or Railroad Retirement on treatment for their cancer diagnosis. The payments are

linked to quality measures such as patient pain levels, ED visits, etc.

Electronic Patient-Reported Outcomes (ePROS) are one method of implementing value-based care. ePROs help identify patient symptoms more quickly and improve patient outcomes with an opt-in rate of nearly 90%. Another method discussed was dose rounding to the nearest vial size of costly monoclonal antibodies and cytotoxic medications, which decreased waste and resulted in significant cost savings to the practice.

Goals for the future include implementing the enhanced oncology care model, which takes the advantages from the oncology care model with an extra focus on social determinants of health as well as increasing engagement from oncology healthcare team members.

DISCUSSION: Rather than a classic Q&A, engagement after the presentation took the form of a discussion. Most of the discussion centered on the importance of implementing this new model for patients

and how and how implementation should be done. Black described how physicians in the clinic all strive to receive the top score on patient-reported metrics.

TAKEAWAY POINTS:

- The current fee for service reimbursement model favors quantity over quality.
- Instead, a value-based healthcare model places emphasis on patients and outcomes by using high value services.
- Under a value-based healthcare model, payment amounts for practices are linked to quality measures.
- Increasing patient monitoring between visits increases treatment persistence and decreases ED visits and hospitalizations.

Summary by **Nicholas Varisco**, PharmDc (2025), University of Texas at Austin.

SESSION SLIDES: Scan the QR code at right to view slides from this presentation.



Sarcoma Management In The Adolescent & Young Adult Population

PRESENTER: Christy Harris, PharmD, BCOP, FHOPA | Massachusetts College of Pharmacy and Health Sciences, Dana-Farber Cancer Institute

SYNOPSIS: Harris discussed the outcomes and effects of treatment in patients with sarcoma. The concerns and barriers to treatment were examined with select monitoring parameters focused on the Adolescent & Young Adult (AYA) population with sarcoma.

PRESENTATION: Sarcoma is a complex disease with more than 100 different subtypes and rare forms. There is an unexplained drop in survival in the AYA population, while the adult population has shown to have a much higher survival rate. Major concerns for the AYA population include poor survival rate, rarity of disease, lack of clinical trials, high dose intensity, likelihood to be uninsured,

higher risk of late effects and the higher prevalence of the aggressive disease. Medical, social and economic challenges are evident and in need of resources.

These concerns affect treatment and outcomes in patients with sarcoma in addition to chemotherapy toxicities and pharmacokinetics of the AYA population. Major toxicities from chemotherapy are expressed. Patients are monitored for cardiotoxicity, nephrotoxicity, ototoxicity, hepatotoxicity and neurotoxicity.

For example, vincristine has a faster clearance in pediatric patients (body weight <40kg) than in adolescents. Patients on vincristine should consider the hazards of neurotoxicity, for the outcomes are different in pediatrics. Although there are barriers to conducting clinical trials, more are needed and are essential to bring understanding to this population.

DISCUSSION:

Q: What are the hypotheses for the causes in explaining sarcoma in AYA in research of prevention of risk?

A: Sarcoma does not have any risk factors for they are spontaneous somatic mutation. We do not know why they occur.

Q: Do pharmacogenetics play a role in sarcomas in the instance that there are mutations that are druggable?

A: A lot of the mutations that we rarely find have a drug that are on the shelf that target those mutations. As soon as we find a potential target, we go straight for it.

TAKEAWAY POINTS:

- Low survival rates for sarcoma are common in the AYA population when compared to other age groups.
- After diagnosis of sarcoma, there are multiple factors that affect the AYA population.
- More research is needed in this area.

Summary by **Tincy Thankachan**, PharmDc (2024), Campbell University.

SESSION SLIDES: Scan the QR code at right to view slides from this presentation.



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Breaking Down the Inflation Reduction Act

PRESENTER: Jessica Nagro, MPA | PhRMA

SYNOPSIS: Nagro addressed the impact of the Inflation Reduction Act (IRA) on the cancer community, highlighting price setting changes and Part D redesign.

PRESENTATION: President Joe Biden recently signed the IRA with the goal of generating revenue to fight soaring inflation rates. Some of the provisions in the IRA target Medicare drug pricing reform that will take effect in 2026.

The new reform will ultimately impact 80 drugs by 2030. Eligibility criteria include single-sourced drugs with \geq 7 years since U.S. Food and Drug Administration (FDA) approval or single-sourced biologics with \geq 11 years since FDA approval from both Part B and D high-cost lists.

The U.S. Department of Health and Human Services has been tasked with determining eligible drugs. Following selection, the manufacturers will be required to submit information to establish a maximum fair price (MFP). Refusal to follow MFP will result in either payment of a hefty tax or removal of all manufacturer medications from the Medicare/Medicaid formulary. Selected drugs will be published on the Centers for Medicare & Medicaid Services website

Medicare Part D redesign includes a \$2,000 beneficiary out-of-pocket cap, smoothing measures (maximum monthly cap) and \$35 insulin copay cap. Overall, these provisions are designed to decrease out-of-pocket costs, increase manufacturer rebates and decrease federal government reinsurance.

While patients will experience savings, undesired outcomes have been predicted for manufacturers. With the anticipated decrease in revenue, manufacturers will not be able to reinvest as much into research and development. Consequently, fewer new medicines are expected to be produced in the United States. Oncology medications are broadly expected to be selected. This causes concern that oncology pipelines may not as robust as they currently are. Additionally,

compensation for cancer care providers is predicted to decrease up to 42%.

DISCUSSION:

Q: What action step can oncology professionals make?

A: NCODA has an impressive record with federal officials, therefore reaching out to NCODA staff or contacting your local legislator can make an impact.

TAKEAWAY POINTS:

- The implementation of the Inflation Reduction Act will impact Medicare drug pricing
- Medicare Part D redesign will result in savings for patients while manufacturers will experience uncertainties.

Summary by **Olivia Bukowski**, PharmDc (2024), University of Toledo.

SESSION SLIDES: Scan the QR code at right to view slides from this presentation.



Cardio-Oncology Pearls & Nutrition in GI Oncology

PRESENTERS: Mayret Gonzalez, PharmD, BCPS | Miami Cancer Institute and Baptist Health South Florida; Lauren Fay, RD-AP, CSO, CNSC | Inova Schar Cancer Institute

SYNOPSIS: Gonzalez discussed cardiac dysfunction related to five different classes of cancer treatment. Fay discussed barriers to nutrition intake in patients with GI cancers.

PRESENTATION: Gonzalez discussed cardiovascular (CV) toxicities associated with anthracyclines, HER2_i, proteasome inhibitors, tyrosine kinase inhibitors (TKIs) and antimetabolites. Risk Stratification of high/very high, moderate or low risk determines whether patients start therapy and frequency of monitoring. Monitoring such as EKGs and echocardiograms differs between drugs. Toxicities vary, including heart failure, atrial fibrillation, sudden cardiac death and more. Anthracyclines typically causes irreversible toxicities and cumulative doses should be evaluated. HER2_i causes reversible toxicities and ejection

fraction determines changes in treatment. Patients on proteasome inhibitors should have a clinical assessment to monitor toxicities every visit. For TKIs, drug interactions must be assessed, and toxicities differ in VEGFi, BCR-ABL and Bruton subclasses. Individuals on antimetabolites should be assessed for atherosclerotic cardiovascular disease. Cardiotoxicity does not end when these treatments are finished.

Fay discussed nutritional priorities in GI cancers, with an emphasis on calories and protein intake. Weight loss can lead to worse performance on cancer therapy. Up to 80% of patients experience malnutrition. Medical nutrition therapy, if needed, should be provided by a registered dietician. Interventions can improve treatment side effects, number of hospitalizations, and quality of life. Factors preventing adequate nutrition include anorexia, nausea and vomiting, bowel irregularities, dysgeusia and pancreatic exocrine insufficiency. Some strategies are maximizing calories and protein in foods and drinks, avoiding

strong odors, and eating fiber. Patients often require a combination of medications and nutritional support.

DISCUSSION:

Q: Is there any data on cardiotoxicity based on race and ethnicity? Is this a factor when assessing a patient for cardiac risk?

A: We currently do not evaluate risk based on race and ethnicity. Medications that work better in certain populations and treatments can be tailored to these differences.

TAKEAWAY POINTS:

• GI cancers can cause difficulties maintaining adequate nutrition

Summary by **Melanie King**, PharmDc (2025), Memorial University in Newfoundland.

SESSION SLIDES: Scan QR codes to view slides from these presentations.





Understanding Updates to USP 797 and 800

PRESENTERS: Brenda Jensen, CPhT, CNMT, MBA | Copmpounding Consultants; Selma Mitiche, PharmD | US Pharmacopeia

SYNOPSIS: This session described the revisions to USP 797 and 800, including all the necessary standards to know about sterile and hazardous drugs to protect patients and healthcare workers who come in contact with them.

PRESENTATION: USP 797 refers to the minimum standards for compounded sterile products (CSPs) to ensure the safety and quality of any individual involved in the storage, handling, preparation, or transportation of these products. USP 797 is divided into different sections with each section having a specific topic of guided information to follow. CSPs are divided into one of three categories with distinct details pertaining to each category. Updated information includes beyond-use dates, minimum amounts of training and garbing requirements, air exchange rates, ISO class

minimum settings, compounding records, immediate use CSP, etc.

USP 800 is similar to USP 797 in its mission on safe handling of drugs, except it focuses on the safety of individuals who come in contact with hazardous medications Hazardous medications are defined as drugs that falls into one of five categories displaying a toxic characteristic. These medications can be found on the NIOSH list of hazardous drugs. Updates to USP 800 include precautions on room requirements, personal protective equipment, drugs that qualify for assessment of risk and drugs that do not qualify, cleaning minimum conditions, etc. Focusing attention on these standards is how healthcare professionals continue to improve the medical profession.

DISCUSSION:

Q: How can pharmacy technicians stay up to date on these changes?

A: Healthcare facilities and personnel can stay up to date with these changes by

signing up for USP updates and exploring the education they have to offer at www.usp.org/compounding.

TAKEAWAY POINTS:

- USP 797 & 800 are the minimum standards placed in healthcare to minimize harm for the preparation of CSP and hazardous drugs while ensuring high quality and safe medications.
- Updates to these requirements are constantly changing to keep patients and healthcare workers safe.
- Enforcing these standards in healthcare facilities will improve medical care and patient outcomes while emphasizing safety and care to everyone involved.

Summary by **Natalie Young**, PharmDc (2024), Binghamton University.

SESSION SLIDES: Scan the QR code at right to view slides from this presentation.



Oncology Pharmacy Technician Certification Prep

PRESENTERS: Janine Brodeur, CPhT, COPhT | cCARE; Taryn Newsome, CPhT | NCODA

SYNOPSIS: Newsome and Brodeur discussed the Oncology Pharmacy Technician Certification Program's two training domains. Domain I encompasses Core Oncology Pharmacy Training and Domain II emphasizes clinical oncology skills and patient management.

PRESENTATION: The Oncology Pharmacy Technician Certification program requires applicants to have at least 12 months of oncology pharmacy experience (or 24 months if not a CPhT) and meet state licensure requirements. The program consists of an application fee, an exam fee and proof of employment. Approved applications are valid for six months and successful applicants receive a digital badge and certificate.

Domain I focuses on pharmaceutical

calculations, hazardous drugs and the Risk Evaluation and Mitigation Strategy (REMS) program. Pharmaceutical calculations include body surface area, weight unit conversion and dosing adjustments of renal excreted medication using the Cockcroft-Gault Equation. Hazardous drugs used in cancer treatment can cause toxicities, requiring oncology pharmacy technicians to ensure safe handling, administration and disposal while wearing proper PPE to minimize exposure.

Domain II covers laboratory values and diagnostic imaging studies related to oral oncolytics, warnings, precautions, and a grading system for adverse events. CBC and CMP are highlighted laboratory values, with imaging studies like PET/CT scan, bone scan and MRI. The warnings and precautions section discussed the potential serious side effects that may occur while taking the medicine. The Common Terminology Criteria for Adverse Events provides a quideline for the severity of adverse

events, ranging from mild to life-threatening consequences or death (Grades 1 through 5).

DISCUSSION:

Q: According to the National Institute of Occupational Safety and Health (NIOSH), what characteristics of a drug make it hazardous?

A: NIOSH considers a drug hazardous if it exhibits one or more of the following characteristics in humans/animals: carcinogenicity, developmental or reproductive toxicity, organ toxicity at low doses, and genotoxicity.

TAKEAWAY POINTS:

• The Oncology Pharmacy Technician Certification Program improves a pharmacy technician's knowledge of oral oncolytic patient management knowledge.

Summary by **Sangnya Upadhyaya**, PharmDc (2023), Temple University.

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Toxicity Management for CAR-T and Bispecific Treatment

PRESENTER: Teresa Thakrar, PharmD, BCOP | Indiana University Simon Cancer Center

SYNOPSIS: Thakrar provided an overview of the mechanism of action for CAR-T and bispecific T-cell engager (BiTE) therapies. The signs and symptoms of cytokine release syndrome (CRS) and neurotoxicity, the management of such toxicities, and clinical considerations associated with CAR-T and BiTE therapy toxicity management were discussed.

PRESENTATION: CAR-T and BiTE therapy are immunotherapies indicated for blood cancers such as leukemia, lymphoma and multiple myeloma with the first U.S. Food and Drug Administration approval occurring in 2014 (blinatumomab).

Common toxicities for these therapies include CRS, neurotoxicity (immune effector cell-associated neurotoxicity syndrome — iCANS), infections, cytopenia and hypogammaglobulinemia.

Common signs and symptoms for CRS include onset fever, hypotension, hypoxia and end organ dysfunction, generally occurring within one week. Common signs and symptoms of iCANS include early tremor and difficulty speaking/swallowing occurring approximately four days after therapy. Symptoms can progress to aphasia, stupor, and coma. Extensive assessments and labs are needed for CRS and iCANS monitoring and to gauge toxicity severity throughout the treatment process. CRS is more frequent, but iCANS is generally more severe.

Thakrar emphasized management of CRS and iCANS. Common medications used to treat toxicities include corticosteroids, broad spectrum antibiotics, antivirals and/or antifungals (for infectious complications and prophylaxis), levetiracetam (iCANS), and tocilizumab (CRS). A REMS Program for CAR-T and BiTE therapy are required due to CRS and iCANS severity.

DISCUSSION:

Q: What are the challenges in initiating

cellular therapies in one's practice?

A: Lack of experience with utilizing CAR-T and BiTE therapies and the amount of monitoring needed pose as challenges.

Q: What advice do you have for practices?

A: Having a multidisciplinary team for around-the-clock care and arranging the patient/caregiver to be proximal to your institution can aid in managing toxicity and outpatient treatment.

TAKEAWAY POINTS:

- CAR-T and BiTE therapy are novel treatment options for blood cancers.
- CRS occurs at a high rate but is mild to moderate for most patients.

Summary by **Javier Granados II**, PharmDc (2024), University of Texas at Austin.

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The Ins and Outs of Managing Financial Assistance and Prior Authorizations

PRESENTERS: Aaron Ginsberg, PharmD | Scripps Health; Yen Nguyen, PharmD | Oncology Consultants; Amy Terhune, CPhT | Florida Cancer Specialists & Research Institute

SYNOPSIS: Ginsberg, Nguyen and Terhune discussed the process and tips for prior authorization and how to help patients save with oncolytic therapies.

PRESENTATION: Prior authorizations (PAs) are obtaining approval for medication through the patient's healthcare plan before dispensing. The PA begins when the prescription is sent to the pharmacy, processed, and tasked to a PA team. It is essential to have a process for PAs to help define responsibilities, create expectations/performance measurements and connect to annual evaluations.

The submission can be completed by electronic prior authorization, blank forms via fax or phone. When building the submission,

utilize reference guides, medication package inserts, NCCN guidelines and current research articles. Once approved, payable claims will be notified, information recorded and the patient contacted regarding copay cards. If denied, the team will submit an appeal as directed by the provider. Tips include having a standardized appeal letter, utilizing literature, lines of therapies, having "urgent" for a 72-hour response and using company letterhead.

If the PA request is from an outside specialty pharmacy, hold functionality, ensure entry of the request, set prioritization based on patient needs, and verify if in doubt.

The presenters also highlighted their use of the Low-income Subsidy Medicare Extra Help Savings Plan (LIS), which the social security administration manages. To qualify, the patient must have an income <135% federal poverty level and be enrolled in the Medicare part D plan. LIS can lead to no monthly premiums or annual deductibles, low copays, no donut hole for drugs, and reimbursements on prior med-

ications. This program must be reapplied annually with the purple letter mailed to the patient. If they do not qualify, patient assistance programs (copay, compassionate drug, benefit verification programs) are utilized with high copay amounts.

DISCUSSION:

Q: What is the common time frame for responses for the LIS program?

A: For some, it can take three to six weeks by mail, for others, up to three months, depending on the state.

TAKEAWAY POINTS:

- XA standard process for PAs is essential for your practice.
- LIS can help low-income patients overcome price barriers.

Summary by **Gage McInturff**, PharmDc (2023), University of North Texas.

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