

**BOARD OF PHARMACY SPECIALTIES
ONCOLOGY PHARMACY SPECIALIST CERTIFICATION
CONTENT OUTLINE/CLASSIFICATION SYSTEM
FINALIZED SEPTEMBER 2016/**FOR USE ON FALL 2017 EXAMINATION AND FORWARD****

UNDERSTANDING THE CONTENT OUTLINE/CLASSIFICATION SYSTEM

The following domains, tasks, and knowledge statements were identified by the BPS Specialty Council on Oncology Pharmacy and validated through a role delineation study, most recently updated in 2016. The proportion of examination items allotted to each domain was determined through analysis and discussion of the results of the role delineation study by the Specialty Council.

Each of the major areas/domains of oncology pharmacy practice noted below will be tested. Questions will not be grouped by domain. Items testing each domain are distributed throughout the total examination. Please note that this examination will **SAMPLE** a candidate's knowledge rather than trying to test all of his/her knowledge.

Here is a brief primer to understand the structure of the content outline/classification system.

Domains: A domain is a major responsibility or duty. You can think of a domain as a major heading in an outline format. You will see the domains displayed as black bars on the outline. Five domains are included in the content outline and are noted below.

1. Pathophysiology and Molecular Biology of Cancer (20 percent of examination)
2. Therapeutics, Patient Management, and Education (38 percent of examination)
3. Clinical Trials and Research (14 percent of examination)
4. Practice Management (22 percent of examination)
5. Public Health (6 percent of examination)

Tasks: A task statement defines an activity that elaborates on the domain or subdomain. The set of task statements in a domain offer a comprehensive and detailed description of the domain. You will see the tasks displayed as light gray bars on the outline.

Knowledge Statement: For each task, it is valuable to understand what knowledge and skills are essential to competent performance. The set of knowledge statements clarifies the expectations for newly certified pharmacists. You will find the knowledge statements under each task statement.

DESCRIPTION

Domain I: Pathophysiology and Molecular Biology of Cancer. Identify the pathophysiological and molecular information that is needed to establish an appropriate and individualized treatment plan for cancer patients.

Task 1: Apply knowledge of oncology literature to identify the information needed about pertinent pathophysiology and molecular biology in order to optimize patient care.

Knowledge of:

1. Etiology and pathophysiology of cancer and cancer-related complications
2. Cancer-related molecular biology and testing
3. Molecular pathways affected by drug therapy
4. Cancers, including staging, diagnosis, prognosis

Task 2: Use genomic (i.e., germline and somatic) and molecular (i.e., prognostic and predictive) test results in order to optimize therapeutic decision making for individual patients.

Knowledge of:

1. Molecular heterogeneity of cancer
2. Somatic and germline aberrations
3. Next generation sequencing technologies
4. Genomics, transcriptomics, proteomics, pharmacogenomics
5. Prognostic tests and data
6. Predictive tests and data
7. Liquid biopsies (e.g., Cell-Free DNA, Circulating Tumor Cells)
8. Passenger and driver aberrations

Task 3: Assess situations that require companion diagnostics in order to enhance the value and effectiveness of therapy.

Knowledge of:

1. Cancer therapies that require a companion diagnostic test
2. Appropriate use and interpretation of biologic tests with respect to treatment decision making
3. Adverse impact if tests are not used or test results are not used appropriately

Task 4: Identify potential mechanisms of tumor resistance in order to design or modify pharmacotherapeutic regimens.

Knowledge of:

1. Mechanisms of tumor resistance
2. Implications of resistance with respect to treatment decision making

Domain II: Therapeutics, Patient Management, and Education. Optimize drug therapy for all patients with cancer through the design, recommendation, implementation, monitoring, and modification of individualized pharmacotherapeutic (treatment and supportive) plans in collaboration with the multidisciplinary healthcare team, and through the education of patients, caregivers, healthcare providers, and trainees.

Task 1: Establish therapeutic goals related to pharmacotherapeutic plans in order to determine appropriate treatment.

Knowledge of:

1. Cancer-specific pathology results, molecular biology and testing
2. Patient-specific oncologic history and current diagnosis
3. Factors that influence treatment goals (e.g., comorbidities, performance status, allergies, adherence)

DESCRIPTION
4. Disease-specific, social, educational, cultural, and financial factors that influence treatment decisions and outcomes
5. Expected treatment-dependent efficacy and safety outcomes
6. Palliative and end-of-life care
<i>Task 2: Design or modify evidence-based individualized pharmacotherapeutic plans based on the assessment of pertinent patient information by integrating pathophysiological, pharmacologic, pharmaco-genomic, -kinetic, -dynamic, and -economic considerations.</i>
Knowledge of:
1. Cancer-specific pathology results, molecular biology and testing
2. Patient-specific oncologic history and current diagnosis
3. Factors that influence treatment goals (e.g., comorbidities, performance status, allergies, adherence)
4. Disease-specific, social, educational, cultural, and financial factors that influence treatment decisions and outcomes
5. Expected treatment-dependent efficacy and safety outcomes
6. Current treatment guidelines and literature
7. Pharmacotherapies and other treatment modalities related to cancer treatment and supportive care
8. Complementary and alternative therapies
9. Drug resistance
10. Drug interactions
11. Toxicity grading and assessment
12. Drug administration and routes of delivery
<i>Task 3: Use prevention and monitoring strategies to address complications and toxicities in order to optimize treatment outcomes.</i>
Knowledge of:
1. Prevention strategies
2. Monitoring strategies
3. Cancer complications
4. Treatment-related complications
5. Toxicity grading and assessment
<i>Task 4: Establish survivorship care plans and associated management strategies.</i>
Knowledge of:
1. Short- and long-term complications
2. Cancer screening and follow up in survivors
3. Application of current survivorship guidelines and literature
4. Pharmacotherapies related to survivorship
5. Nonpharmacological treatments
<i>Task 5: Educate patients and caregivers regarding pharmacotherapeutic plans.</i>
Knowledge of:
1. Pharmacotherapeutic regimens, schedules and anticipated complications
2. Prevention, and management techniques of cancer-related complications
3. Cancer staging, diagnosis, prognosis, and treatments
4. Complementary/alternative medicines

DESCRIPTION
5. Toxicity grading and assessment
6. Drug administration, interactions, and routes of delivery
7. Hazardous drug handling and disposal techniques
8. Social, educational, cultural and financial factors that may influence treatment decisions.
9. Appropriate educational techniques and assessment of comprehension
<i>Task 6: Provide training and education to trainees and health care providers regarding oncologic treatment and supportive care.</i>
Knowledge of:
1. Effective educational techniques appropriate for learners needs and learning style
2. Development of learning objectives and assessment strategies
3. Pharmacotherapeutic regimens, schedules and anticipated complications
4. Prevention, and management techniques of cancer-related complications
5. Cancer staging, diagnosis, prognosis, and treatments
6. Complementary/alternative medicines
7. Toxicity grading and assessment
8. Drug administration, interactions, and routes of delivery
9. Hazardous drug handling, BUD, and disposal techniques
10. Social, educational, cultural and financial factors that may influence treatment decisions.
11. Appropriate educational techniques and assessment of comprehension
Domain III: Clinical Trials and Research. Contribute to the care of patients with cancer through the generation, design, and analysis of studies, and the interpretation, integration, and dissemination of research findings related to oncology.
<i>Task 1: Evaluate the literature with regard to study design, methodology, and statistical analysis in order to determine the applicability of results to the oncology population.</i>
Knowledge of:
1. Methods for and considerations in conducting literature searches
2. Types of observational and interventional studies
3. Study design (e.g., hypothesis generation, limitations)
4. Internal and external validity
5. Relevance of the patient population
6. Calculation and interpretation of biostatistics in medical literature
7. Graphical representations in oncology literature
8. Endpoints of research studies
9. Clinical significance and statistical significance
<i>Task 2: Apply knowledge of the drug development process as it relates to oncology clinical trials.</i>
Knowledge of:
1. Phases of, objectives for, and design of oncology clinical trials
2. Study designs that incorporate genomics
3. Approval of investigational new drugs
4. Approval of biosimilars
5. Collaborative trial groups
<i>Task 3: Perform scholarly activities in order to promote patient-centered care.</i>
Knowledge of:
1. Identification of gaps in the literature (i.e., unanswered research questions)

DESCRIPTION
2. Design of a hypothesis-driven research study
3. Venues and processes for disseminating new information (e.g., publication, presentations)
<i>Task 4: Apply knowledge of regulations as they pertain to the conduct of research and clinical trials.</i>
Knowledge of:
1. Role of the Institutional Review Board (IRB) and regulatory bodies
2. Compliance with policies and procedures of the IRB and regulatory bodies
3. Ethical issues related to the conduct of research and clinical trials
4. Investigational drug management
Domain IV: Practice Management. Establish, implement, and monitor systems, policies, and procedures to ensure the safe, effective, and appropriate use of medications for patients with cancer and the integration of value and access into clinical decision making.
<i>Task 1: Establish institutional drug-use guidelines, policies, procedures, and formularies that are consistent with evidence, regulation, and/or current practice guidelines and standards in collaboration with other stakeholders.</i>
Knowledge of:
1. Clinical practice guidelines and best practices for cancer treatment and supportive care
2. National accreditation and regulatory organizations and their requirements
3. Professional practice standards and guidelines for safety (e.g., ASCO-ONS Standards for Safe Chemotherapy Administration, ASHP Guidelines on Handling Hazardous Drugs, USP 800, NIOSH)
<i>Task 2: Maintain systems and technology to ensure the safety and effectiveness of the oncology medication use process.</i>
Knowledge of:
1. Electronic health information systems
2. Medication Use Evaluation, root cause analysis, ISMP communications, and other quality improvement strategies
3. Technologies that enhance the safety and quality of the dispensing process
4. Requirements for staff competence with regard to oncology pharmacy practice consistent with professional practice standards
5. Chemotherapy order set development and maintenance
<i>Task 3: Apply knowledge of the procurement and reimbursement of oncology medications and services in order to optimize health care cost effectiveness.</i>
Knowledge of:
1. Medication reimbursement models
2. Pharmacy purchasing (e.g., PHS pricing, GPO contracts)
3. Reimbursement for clinical pharmacy services
4. Specialty pharmacy services
<i>Task 4: Optimize processes in order to ensure the availability of oncology medications for patients.</i>
Knowledge of:
1. Patient assistance programs
2. Drug shortage management
3. Risk Evaluation Mitigation Strategy (REMS) programs
4. Compassionate use processes
Domain V: Public Health. Contribute to public health knowledge by providing information about cancer prevention, screening, and early detection.
<i>Task 1: Apply knowledge about cancer prevention, screening, and early detection strategies.</i>

DESCRIPTION
Knowledge of:
1. Modifiable and non-modifiable risk factors
2. Prevention strategies
3. Screening guidelines
4. Early detection strategies
<i>Task 2: Inform the public about reliable sources of information and cancer-support organizations.</i>
Knowledge of:
1. General resources to be used in informing the public about cancer and its treatment
2. Cancer-support organizations and resources