Domain 1: Biotherapies in the Patient Care Ecosystem

DOMAIN WEIGHTING: THIS DOMAIN COVERS 11% OF THE EXAM.

Objectives

The following represent content areas and tasks and skills evaluated in the examination.

1.1 Educates patients, caregivers, colleagues, and others regarding the unique mechanisms of action in biotherapies, including distributive processes, product characteristics, risk and efficacy, and the entire process of collection/acquisition, research, manufacture, delivery, and administration.

- Given a scenario about educating a patient regarding unique mechanisms of action in biotherapies, identify how the risk and efficacy should be explained to the patient.
- Given a scenario about educating a patient regarding unique mechanisms of action in biotherapies, identify how the delivery and administration should be explained to the patient.
- Given a scenario about educating a patient regarding unique mechanisms of action in biotherapies, identify how the human subject research (clinical trial) should be explained to the patient.
- Given a scenario about educating a caregiver regarding unique mechanisms of action in biotherapies, identify how the side effects (risk/adverse events) should be explained to the caregiver.
- Given a scenario about educating a caregiver regarding unique mechanisms of action in biotherapies, identify how the distributive process or product characteristics should be explained to the caregiver.
- Given a scenario about educating a colleague regarding unique mechanisms of action in biotherapies, identify how the delivery process should be explained to the colleague.
- Given a scenario about educating a colleague regarding unique mechanisms of action in biotherapies, identify how the administration process should be explained to the colleague.

1.2 Connects biotherapy medicine and techniques to individual patient needs through coordination and bi-directional communication with multidisciplinary peers.

- Given a scenario where a patient is prescribed a biotherapy, identify steps that must be coordinated with other healthcare providers.

- Given a scenario where a patient is prescribed a biotherapy, identify the information that should be communicated to the prescriber.

1.3 Translates standards of quality and regulation into individualized care, including route of administration, administration rates, premedication, and Risk Evaluation and Mitigation Strategies (REMS).

- Given a scenario about a patient including a biotherapy, identify the routes of administration that could impact standards of quality and regulation.
- Given a scenario about a patient including a biotherapy, identify the premedication that could impact standards of quality and regulation.
- Given a scenario about a patient including a biotherapy, identify the symptoms that may present in the REM strategy.

1.4 Facilitates patient navigation to reduce barriers to care and support adherence to treatment protocols.

- Given a scenario when a patient must have a caregiver to complete treatment procedures, identify the various forms of care resources that can reduce barriers.

1.5 Verifies suitability of biotherapy product and the patient condition prior to infusion.

1.6 Supports and performs product administration (including actual infusion when appropriate) and provides monitoring care/oversight for adverse events.

- Given a scenario where the product is administered intravenously, identify possible adverse reactions related to the route of administration.

1.7 Monitors post-administration effects and makes adaptations as needed recognizing potential reactions (immunological and non-immunological).

- Given a patient who has received a biotherapy, identify some of the immunological side effects that may be experienced and how to recognize them.
- Given a patient who has received a biotherapy, identify some of the non-immunological side effects that may be experienced and how to recognize them.

1.8 Engages patients and their families in long-term follow-up to inform longitudinal experiences with biotherapies.

- Given a patient who has received a biotherapy, identify the activities that may be involved in long-term follow-up.

Key Terms

Adverse event: A suspected or proven unfavorable response to the procurement or administration of cellular therapy products, manifested by signs or symptoms.

Caregiver: Anyone who gives care to someone who needs help taking care of themselves.

Distribution (pharmacology): The reversible transfer of a drug from one location to another within the body.

Mechanism of action: Pharmacologic action at the receptor, membrane, or tissue level; an explanation of how a drug causes specific changes in the body.

Prescribing information/package insert: Summarizes the information health-care providers need to use the drug safely and effectively.

Quality: The suitability of either a drug substance or drug product for its intended use. This term includes such attributes as the identity, strength, and purity (ICH Q6A).

Risk and efficacy: Information that numerically addresses the likelihood or magnitude of a drug's efficacy or risks.

Risk Evaluation and Mitigation Strategy (REMS): A drug safety program that the US 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.

Suitability: Suitability of a biotherapy for a patient depends upon several factors, including disease status, patient medical history and current physiology, biomarkers, psychological status, and financial and caregiver considerations.

Note: Definitions are compiled from this chapter, AABB *CT Standards*, and other sources.

Overview

Those who take the CABP exam already have some experience working in some capacity in the cellular and gene therapy community. They have some familiarity with what is happening during their part of the process. But they may not always know what happens down the line or what happened before their process begins. From that perspective, below are a few broad suggestions.

This chapter offers a general process for preparing for the exam on this domain. It may not contain all that you will need to know but is meant to help you develop your own study plan and point you toward references for further research. Content is classified by each of the eight objectives. See the reference list at the end of the chapter for relevant sources.

Walk-Through of Domain 1 Objectives

1.1 Providing Education

Exam Objective	
1.1 Educates patients, caregivers, colleagues, and others regarding the unique mechanisms of action in biotherapies, including distributive processes, product characteristics, risk and efficacy, and the entire process of collection/acquisition, research, manufacture, delivery, and administration.	
Given a scenario about educating _____ regarding unique mechanisms of action in biotherapies,	identify how _____ should be explained.
o a patient	1) the risk and efficacy 2) the delivery and administration 3) the human subject research (clinical trial)
o a caregiver	1) the side effects (risk/adverse events) 2) the distributive process or product characteristics
o a colleague	1) the delivery process 2) the administration process
How do we do this in our system? **Communication.**	

Each type of participant has a unique part in the cellular therapy and gene therapy process. The patient needs to understand the process, not necessarily the technical information, although some may be intrigued by it as naturally curious individuals. The key word that describes what medical professionals do in this section is **communicate**. It takes communication and a certain level of understanding for a patient to consent to this type of treatment—and "treatment" is used here vs "drug" because cellular and gene therapies are a **process** rather than merely receiving an infusion or taking a pill. Patients and their families must commit to the process, and it is the job of medical professionals to communicate that and educate them on that process.

Also, because there are many different processes in the manufacture of these new and exciting therapies, how do professionals communicate with each group and what does each member need to know? The laboratory may or may not need