

CE/CME QUESTIONS

Managing the Expanded Use of Biologics Across Therapeutic Areas: An Example From B-Cell Targeted Therapies
Method of Participation:

Participants must:

- Read the learning objectives and faculty disclosures.
- Study the educational activity.
- Complete and submit the post-test with a pass rate of 70% or higher.
- Complete and submit the evaluation forms.
- Complete and submit the attendance verification form.

A statement of credit will be issued only upon receipt of completed evaluation forms, a completed post-test with a score of 70% or higher, and a completed attendance verification form. Your statement of credit will be e-mailed to you 6 to 8 weeks after receipt.

Instructions

After reading "Managing the Expanded Use of Biologics Across Therapeutic Areas: An Example From B-Cell Targeted Therapies," please complete the program evaluation and circle the 1 best answer to each of the following questions.

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1. **Biopharmaceuticals are most commonly defined as:**
 - a) Drugs that are produced through biological processes that structurally replace compounds within the body.
 - b) Drugs that are produced through biological processes that structurally mimic compounds within the body.
 - c) Drugs that are produced through artificial processes that assist in disease treatment.
 2. **Omalizumab is approved for which of the following indications?**
 - a) Moderate-to-severe persistent allergic asthma and prevention of peanut-induced allergic reactions
 - b) Moderate-to-severe persistent allergic asthma
 - c) Moderate-to-severe persistent allergic asthma and allergic rhinitis
 - d) Allergic rhinitis and prevention of peanut-induced allergic reactions
 - e) Prevention of peanut-induced allergic reactions
 3. **Exenatide, an injectable incretin mimetic, was approved in 2005 for the adjunctive treatment of:**
 - a) Type 1 diabetes.
 - b) Type 1 and 2 diabetes.
 - c) Type 2 diabetes.
 4. **Which of the following drug categories slow or halt the progression of rheumatoid arthritis?**
 - a) Disease-modifying antirheumatic drugs (DMARDs), biologic response modifiers, analgesics, costimulation modulators, interleukin (IL)-1 blockers
 - b) Glucocorticoids, DMARDs, analgesics, B-cell targeting
 - c) DMARDs, biologic response modifiers, glucocorticoids, costimulation modulators, B-cell targeting, IL-1 blockers
 - d) Analgesics, glucocorticoids, biologic response modifiers, IL-1 blockers
 5. **Which of the following agents are approved for patients with rheumatoid arthritis who have inadequate response to methotrexate?**
 - a) Infliximab
 - b) Etanercept
 - c) Rituximab
 6. **B-cell blockers have the potential to be used as treatment in many different diseases.**
 - a) True
 - b) False
 7. **Which of the following diseases is the top target of biopharmaceuticals in late-stage development?**
 - a) Diabetes
 - b) Heart disease
 - c) Cancer
 - d) Rheumatoid arthritis
 8. **Etanercept is approved for which of the following disease states?**
 - a) Adult rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and adult plaque psoriasis
 - b) Adult rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis
 - c) Ankylosing spondylitis, psoriatic arthritis, and adult plaque psoriasis
 - d) Adult rheumatoid arthritis
 9. **Rosiglitazone is currently under investigation for which of the following?**
 - a) Plaque psoriasis
 - b) Type 1 diabetes
 - c) Type 2 diabetes
 10. **Traditionally, infused drugs have been covered under which of the following benefit types?**
 - a) Medical
 - b) Pharmacy

CE/CME EVALUATION



University of Utah College of Pharmacy
University of Utah School of Medicine



Journal Evaluation Form

Managing the Expanded Use of Biologics Across Therapeutic Areas:
An Example From B-Cell Targeted Therapies

ACPE Program Number: 068-999-05-049-H01 (1.5 contact hours – 0.15 CEUs)

DATE OF COMPLETION OF EDUCATION PROGRAM: _____

Please rate the extent to which you are now able to meet each of the program objectives using the scale below:

1 (Strongly Disagree) to 4 (Strongly Agree) for each item.

- Understand how the use of biologic therapies is expanding dramatically. 1 2 3 4
- Recognize that common physiologic mechanisms are implicated in many disease states and are common targets for expanding indications for FDA-approved therapies. 1 2 3 4
- Describe the challenges for managed care pharmacy in managing the differing costs, benefit designs, contracts, modes of delivery, and management strategies of drugs with multiple indications. 1 2 3 4
- Understand the benefits to managed care pharmacy associated with usage expansion, real-world knowledge of that drug, and potentially more competitive contracting arrangements. 1 2 3 4
- Review study data of the B-cell targeted therapy rituximab. 1 2 3 4
- Describe aspects of a management plan for dealing with implications of expanded indications for formulary decision makers. 1 2 3 4

Please rate the program on a scale of 1 (Strongly Disagree) to 4 (Strongly Agree) for each item:

- The program was well-administered by staff. 1 2 3 4
- This program enhances my professional effectiveness. 1 2 3 4
- The program used visual aids effectively. 1 2 3 4
- The instructional process is one of high quality. 1 2 3 4

1. Was the program free from commercialism and bias? (Yes/No) If no, please explain.

2. What did you like about this program?

3. Was there something you did not like about this program?

4. Please list 1 or more topics that you would like to see covered in future continuing education programs.

Thank you!

CE/CME EVALUATION

University of Utah College of Pharmacy Continuing Education The University of Utah Continuing Medical Education

Journal Article Education Activity Statement of Credit Request

Managing the Expanded Use of Biologics Across Therapeutic Areas: An Example From B-Cell Targeted Therapies
ACPE UPN 068-999-05-049-H01

For Pharmacists Only:

I certify my actual time spent to complete this activity to be:

- I participated in this activity and claim 1.5 contact hours (0.15 CEUs)
- I participated in only part of this activity and claim _____ contact hours.

Name of Participant: _____

State of Licensure and License Number: _____

Phone Number and E-mail Address: _____

Date of Completion: _____

Participant Signature: _____

For Physicians Only:

I certify my actual time spent to complete this educational activity to be:

- I participated in the entire activity and claim 1.5 credits.
- I participated in only part of this activity and claim _____ credits.


Name of Participant: _____

Phone Number and E-mail Address: _____

Degree Status and Specialty: _____

Date of Completion: _____

Participant Signature: _____

 The University of Utah College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Mail or fax completed form to:
University of Utah College of Pharmacy CE Office
421 Wakara Way, Suite 208, Salt Lake City, Utah 84108
Fax: 801-581-3716

Digital certificates will be processed by the responsible party and e-mailed directly to participants.
Allow up to 6 to 8 weeks for processing.

CONTINUING EDUCATION

Managing the Expanded Use of Biologics Across Therapeutic Areas: An Example from B-Cell Targeted Therapies

GOAL

To enhance understanding of the therapeutic targets common to many disease states that have led to expanded indications for many already approved drugs and the clinical and management challenges of using biologics with multiple indications.

TARGET AUDIENCE

Managed care pharmacy directors, medical directors, and other managed care executives responsible for overseeing the use of biologics and managing them on behalf of health plans.

LEARNING OBJECTIVES

Upon completion of this activity, participants will be able to:

- Understand how the use of biologic therapies is expanding dramatically, including the introduction of new products, the approval of additional indications for existing products, and the approval of biologics for more common conditions.
- Recognize that common physiologic mechanisms, such as tumor necrosis factor- α , B-cells, and immunoglobulin E, are implicated in many disease states and are common targets for expanding indications for therapies approved by the US Food and Drug Administration (FDA).
- Describe the challenges for managed care pharmacy in managing the differing costs, benefit designs, contracts, modes of delivery, and management strategies of drugs with multiple indications.
- Understand the benefits to managed care pharmacy associated with usage expansion, such as enhanced clinical outcomes, real-world knowledge of the drug, and potentially more competitive contracting arrangements.
- Review study data of a B-cell targeted therapy, rituximab (approved for non-Hodgkin's lymphoma and under investigation for the treatment of rheumatoid arthritis), as an example of a drug with potentially 2 widely expanded indications.
- Describe aspects of a management plan for dealing with implications of expanded indications for formulary decision makers.

Initial Live Release Date: October 6, 2005

Release Date: April 1, 2006

Expiration Date: March 31, 2007

If the participant has previously attended this program and requested or received credit, he/she may not request or receive credit for the home study version of the program.

FEES

There are no fees associated with this continuing education offering.

FUNDING

Genentech has provided the grant funds for this activity.

Credit Designation:



The University of Utah College of Pharmacy designates this continuing education activity for 1.5 credit hours (0.15 CEUs) of the Accreditation Council for Pharmacy Education. Universal Program Number: 068-999-05-049-H01.

The University of Utah College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The University of Utah School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The University of Utah School of Medicine designates this educational activity for a maximum of 1.5 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

Disclosure of Unlabeled Use:

This educational activity may contain discussion of published and/or investigational uses of agents that are not indicated by the FDA. The University of Utah College of Pharmacy and the University of Utah School of Medicine do not recommend the use of any agent outside of the labeled indications.

MEDIA

Journal article learning activity.