BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 6/19/14**
SECTION: DRUGS	**LAST REVIEW DATE: 5/17/18**
	LAST CRITERIA REVISION DATE: 5/17/18
	ARCHIVE DATE:

BENICAR® (olmesartan medoxomil) oral tablet
BENICAR HCT® (olmesartan medoxomil-hydrochlorothiazide) oral tablet
OLMESARTAN MEDOXOMIL oral tablet
OLMESARTAN MEDOXOMIL-HYDROCHLOROTHIAZIDE oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602)

BENICAR® (olmesartan medoxomil) oral tablet
BENICAR HCT® (olmesartan medoxomil-hydrochlorothiazide) oral tablet
OLMESARTAN MEDOXOMIL oral tablet
OLMESARTAN MEDOXOMIL-HYDROCHLOROTHIAZIDE oral tablet (cont.)

864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Criteria:

- **Criteria for initial therapy:** Benicar or Benicar HCT or Olmesartan medoxomil or Olmesartan medoxomil-hydrochlorothiazide is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. **ONE** of the following:
   - **For Benicar or Olmesartan medoxomil**: Individual is 6 years of age or older
   - **For Benicar HCT or Olmesartan medoxomil-hydrochlorothiazide**: Individual is 18 years of age or older

2. Individual has medical record documentation of a confirmed diagnosis of hypertension

3. **For Benicar or Olmesartan medoxomil,** individual is unable to use **FOUR** of the following preferred ARBs due to failure, contraindication or intolerance:
   - Generic candesartan
   - Generic eprosartan
   - Generic irbesartan
   - Generic losartan
   - Generic telmesartan
   - Generic valsartan
   - Brand Edarbi™ (azilsartan)
   - Brand Micardis® (telmisartan)

4. **For Benicar HCT or Olmesartan medoxomil-hydrochlorothiazide,** individual is unable to use **FOUR** of the following preferred step therapy agents due to failure, contraindication or intolerance:
   - Candesartan-HCTZ
   - Irbesartan-HCTZ
   - Losartan-HCTZ
   - Valsartan-HCTZ
   - Brand Edarbyclor™ (azilsartan-chlorthalidone)
   - Simultaneously use a thiazide-like diuretic as a single agent with **one of the following** trials of a preferred ARB as a single agent
     - Generic candesartan
     - Generic eprosartan
     - Generic irbesartan
     - Generic losartan
     - Generic telmesartan

BENICAR® (olmesartan medoxomil) oral tablet
BENICAR HCT® (olmesartan medoxomil-hydrochlorothiazide) oral tablet
OLMESARTAN MEDOXOMIL oral tablet
OLMESARTAN MEDOXOMIL-HYDROCHLOROTHIAZIDE oral tablet (cont.)

- Generic valsartan
- Brand Edarbi™ (azilsartan)
- Brand Micardis® (telmisartan)

5. Absence of **ALL** of the following contraindications:
   - Simultaneous use with aliskiren in individuals with diabetes
   - Hypersensitivity to any component of Benicar HCT or Olmesartan medoxomil
   - Anuria

Initial approval duration: 30 tablets per month for 12 months

- **Criteria for continuation of coverage (renewal request):** Benicar or Benicar HCT or Olmesartan medoxomil or Olmesartan-hydrochlorothiazide is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Achieved and maintains blood pressure control goal

2. Individual has been adherent with the medication

3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
   - Contraindications as listed in the criteria for initial therapy section
   - Sprue-like enteropathy where no other etiology is found

4. There are no significant interacting drugs

Renewal duration: 30 tablets per month for 12 months

Description:

Benicar (olmesartan), Benicar HCT (olmesartan-hydrochlorothiazide), Olmesartan medoxomil, and Olmesartan medoxomil-hydrochlorothiazide are indicated for the treatment of hypertension.

Hypertension is an important and common treatable disorder. Numerous clinical trials show that controlling hypertension has a beneficial impact on stroke, myocardial infarction, kidney disease, and other vascular diseases. Management of hypertension may include lifestyle modifications such as weight loss, reduction in sodium intake, exercise, and other changes in behavior. Medications may be used singly or in combination when lifestyle modifications are not sufficient to control blood pressure. Many individuals will require more than one drug to achieve blood pressure goals.

BENICAR® (olmesartan medoxomil) oral tablet
BENICAR HCT® (olmesartan medoxomil-hydrochlorothiazide) oral tablet
OLMESARTAN MEDOXOMIL oral tablet
OLMESARTAN MEDOXOMIL-HYDROCHLOROTHIAZIDE oral tablet (cont.)

There are several pharmacologic categories that contain numerous medications within most categories, with many generic formulations to choose from. These pharmacologic categories include: thiazide-type diuretics, angiotensin converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB), calcium channel blockers (CCB), beta-blockers, aldosterone antagonists, vasodilators, alpha-blockers, direct renin inhibitors, and others. Olmesartan is an example of an ARB, while hydrochlorothiazide is a thiazide-type diuretic. There are many other products available that combine drugs from different pharmacologic classes.

Recent guidelines suggest that first line therapy for treatment of hypertension utilize a medication from one of 4 classes. These classes include: thiazide-type diuretic, ACEI, ARB, or CCB. Selection of agents from one of these classes may take into account race and presence of other medical conditions such as chronic kidney disease or diabetes. Combination therapy may be required to achieve blood pressure goals.

Resources:

Benicar product information accessed 04-26-18 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=33770d80-754f-11de-8dba-0002a5d5c51b

Benicar HCT product information accessed 04-26-18 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6bbc032a-3cc4-4b1d-8124-1784214a2821

Olmesartan medoxomil product information accessed 04-26-18 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8dfa070e-3f05-03e8-4c2e-862cb8e0d984

Olmesartan medoxomil and hydrochlorothiazide product information accessed 04-26-18 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=744c1785-42b2-46a5-b0f4-2887a9ec2051

Benicar. Package Insert. Revised by manufacturer 12/2013, reviewed 5/1/14; revised 11/2016, reviewed 5/4/17

Benicar HCT. Package Insert. Revised by manufacturer 7/2013, reviewed 5/1/14; revised 8/2016, reviewed 5/4/17

James PA, Oparil S, Carte BL, et al: 2014 Evidence-based Guideline for the Management of High Blood Pressure in Adults: Report from the panel members appointed to the eighth Joint National Committee (JNC 8). LAMA 2014;311(5):507-520.

Olmesartan medoxomil package insert, revised by manufacturer on 05/2017, reviewed on May 6, 2017

Olmesartan medoxomil-hydrochlorothiazide package insert, revised by manufacturer on 02/2016, reviewed on May 6, 2017

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.