

Effective Date	1/1/2023
Next Review Date	1/1/2024
Coverage Policy Number	IP0362

Angiotensin Receptor Blockers

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following Angiotensin Receptor Blocker products:

- **Atacand**® (candesartan)
- Atacand® HCT (candesartan/hydrochlorothiazide)
- **Avalide**® (irbesartan/hydrochlorothiazide)
- Avapro[®] (irbesartan)
- Azor® (amlodipine/olmesartan)
- Benicar® (olmesartan)
- Benicar HCT® (olmesartan/hydrochlorothiazide)
- Cozaar® (losartan)
- Diovan® (valsartan)
- **Diovan HCT**® (valsartan/hydrochlorothiazide)
- Edarbi® (azilsartan)
- Edarbyclor® (azilsartan/chlorthalidone)
- Exforge® (amlodipine/valsartan)
- Exforge HCT® (amlodipine/hydrochlorothiazide/ valsartan)
- Hyzaar[®] (losartan/ hydrochlorothiazide)

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- Micardis® (telmisartan)
- Micardis® HCT (telmisartan/hydrochlorothiazide)
- **Tribenzor**® (amlodipine/hydrochlorothiazide/olmesartan)
- valsartan 4 mg/mL oral solution

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

The products in the table below are considered medically necessary when the following are met:

Employer Group Non-Covered Products and Preferred Covered Alternatives:

Non-Covered Product	Criteria
Atacand (candesartan)	There is documentation of BOTH of the following (A <u>and</u> B): A. The individual has tried <u>candesartan</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to BOTH of the following: i. losartan ii. valsartan
Atacand HCT (candesartan/ hydrochlorothiazide)	 There is documentation of BOTH of the following (A and B): A. The individual has tried candesartan/hydrochlorothiazide (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. irbesartan/hydrochlorothiazide ii. losartan/hydrochlorothiazide iii. olmesartan/hydrochlorothiazide iv. telmisartan/hydrochlorothiazide v. valsartan/hydrochlorothiazide
Avalide (irbesartan/ hydrochlorothiazide)	Value/Advantage/Cigna Total Savings Drug List Plans: There is documentation of BOTH of the following (A and B): A. The individual has tried irbesartan/hydrochlorothiazide (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. candesartan/hydrochlorothiazide ii. losartan/hydrochlorothiazide iii. olmesartan/hydrochlorothiazide iv. telmisartan/hydrochlorothiazide v. valsartan/hydrochlorothiazide
	Standard/Performance/Legacy Drug List Plans: Step Therapy applies.

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Non-Covered Product	Criteria
Avapro (irbesartan)	Value/Advantage/Cigna Total Savings Drug List Plans: There is documentation of BOTH of the following (A and B): A. The individual has tried irbesartan (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. candesartan ii. losartan iii. olmesartan iv. telmisartan v. valsartan Standard/Performance/Legacy Drug List Plans: Step Therapy applies.
Azor (amlodipine/ olmesartan)	There is documentation of BOTH of the following (A and B): A. The individual has tried amlodipine/olmesartan (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to ALL of the following: i. amlodipine/benazepril ii. amlodipine/telmisartan iii. amlodipine/valsartan
Benicar (olmesartan)	Value/Advantage/Cigna Total Savings Drug List Plans: There is documentation of BOTH of the following (A and B): A. The individual has tried olmesartan (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. candesartan ii. irbesartan iii. losartan iv. telmisartan v. valsartan Standard/Performance/Legacy Drug List Plans: Step Therapy applies.
Benicar HCT (olmesartan/ hydrochlorothiazide)	Value/Advantage/Cigna Total Savings Drug List Plans: There is documentation of BOTH of the following (A and B): A. The individual has tried olmesartan/hydrochlorothiazide (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. candesartan/hydrochlorothiazide ii. irbesartan/hydrochlorothiazide iii. losartan/hydrochlorothiazide

iv. telmisartan/hydrochlorothiazide v. valsartan/hydrochlorothiazide Indard/Performance/Legacy Drug List Plans: In Therapy applies. Index/Advantage/Cigna Total Savings Drug List Plans: In the individual has tried Index
Interapy applies. Interapy appl
ere is documentation of BOTH of the following (A and B): A. The individual has tried losartan (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. candesartan ii. irbesartan iii. olmesartan iv. telmisartan
v. valsartan
undard/Performance/Legacy Drug List Plans: p Therapy applies.
lue/Advantage/Cigna Total Savings Drug List Plans: ere is documentation of BOTH of the following (A and B): A. The individual has tried valsartan (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to BOTH of the following: i. candesartan ii. losartan
ndard/Performance/Legacy Drug List Plans: p Therapy applies.
lue/Advantage/Cigna Total Savings Drug List Plans: ere is documentation of BOTH of the following (A and B): A. The individual has tried valsartan/hydrochlorothiazide (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. candesartan/hydrochlorothiazide ii. irbesartan/hydrochlorothiazide iii. losartan/hydrochlorothiazide iv. olmesartan/hydrochlorothiazide v. telmisartan/hydrochlorothiazide
ep Therapy applies. ere is documentation of EITHER of the following (A <u>or</u> B):

Non-Covered Product	Criteria	
	 A. The individual was recently hospitalized (and discharged within 30 days) for a cardiovascular event (for example, myocardial infarction, hypertensive emergency) who is stabilized on Edarbi. B. The individual has had an inadequate response, contraindication, or is intolerant to FIVE of the following: i. candesartan ii. irbesartan iii. losartan iv. olmesartan v. telmisartan vi. valsartan 	
Edarbyclor (azilsartan/ chlorthalidone)	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to FIVE of the following: A. candesartan/hydrochlorothiazide B. irbesartan/hydrochlorothiazide C. losartan/hydrochlorothiazide D. olmesartan/hydrochlorothiazide E. telmisartan/hydrochlorothiazide F. valsartan/hydrochlorothiazide	
Exforge (amlodipine/ valsartan)	Value/Advantage/Cigna Total Savings Drug List Plans: There is documentation of BOTH of the following (A and B): A. The individual has tried amlodipine/valsartan (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to ALL of the following: i. amlodipine/benazepril ii. amlodipine/olmesartan iii. amlodipine/telmisartan	
Exforge HCT (amlodipine/ hydrochlorothiazide/ valsartan)	Value/Advantage/Cigna Total Savings Drug List Plans: There is documentation of BOTH of the following (A and B): A. The individual has tried amlodipine/hydrochlorothiazide/valsartan (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. generic Accuretic (quinapril/hydrochlorothiazide) and amlodipine concurrently ii. generic Atacand HCT (candesartan/hydrochlorothiazide) and amlodipine concurrently iii. generic Avalide (irbesartan/hydrochlorothiazide) and amlodipine concurrently iv. generic Azor (amlodipine/olmesartan) and hydrochlorothiazide concurrently v. generic Benicar HCT (olmesartan/hydrochlorothiazide) and amlodipine concurrently vi. generic Diovan HCT (valsartan/hydrochlorothiazide) and amlodipine concurrently	

Non-Covered Product	Criteria
	vii. generic Exforge (amlodipine/valsartan) and hydrochlorothiazide concurrently viii. generic Tribenzor (amlodipine/hydrochlorothiazide/valsartan)
Hyzaar (losartan/ hydrochlorothiazide)	Value/Advantage/Cigna Total Savings Drug List Plans: There is documentation of BOTH of the following (A and B): A. The individual has tried losartan/hydrochlorothiazide (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. candesartan/hydrochlorothiazide ii. irbesartan/hydrochlorothiazide iii. olmesartan/hydrochlorothiazide iv. telmisartan/hydrochlorothiazide v. valsartan/hydrochlorothiazide Standard/Performance/Legacy Drug List Plans: Step Therapy applies.
Micardis (telmisartan)	Value/Advantage/Cigna Total Savings Drug List Plans: There is documentation of BOTH of the following (A and B): A. The individual has tried telmisartan (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. candesartan ii. irbesartan iii. losartan iv. olmesartan v. valsartan
Micardis HCT (telmisartan/ hydrochlorothiazide)	Standard/Performance/Legacy Drug List Plans: Step Therapy applies. Value/Advantage/Cigna Total Savings Drug List Plans: There is documentation of BOTH of the following (A and B): A. The individual has tried telmisartan/hydrochlorothiazide (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. candesartan/hydrochlorothiazide ii. irbesartan/hydrochlorothiazide iii. losartan/hydrochlorothiazide iv. olmesartan/hydrochlorothiazide v. valsartan/hydrochlorothiazide Standard/Performance/Legacy Drug List Plans:
Tribenzor	Step Therapy applies. Value/Advantage/Cigna Total Savings Drug List Plans:
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Non-Covered Product	Criteria
(amlodipine/ hydrochlorothiazide/ olmesartan)	There is documentation of BOTH of the following (A and B): A. The individual has tried amlodipine/hydrochlorothiazide/olmesartan (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: i. generic Accuretic (quinapril/hydrochlorothiazide) and amlodipine concurrently ii. generic Atacand HCT (candesartan/hydrochlorothiazide) and amlodipine concurrently iii. generic Avalide (irbesartan/hydrochlorothiazide) and amlodipine concurrently iv. generic Azor (amlodipine/olmesartan) and hydrochlorothiazide concurrently v. generic Benicar HCT (olmesartan/hydrochlorothiazide) and amlodipine concurrently vi. generic Diovan HCT (valsartan/hydrochlorothiazide) and amlodipine concurrently vii. generic Exforge (amlodipine/valsartan) and hydrochlorothiazide concurrently viii. generic Exforge (amlodipine/valsartan) and hydrochlorothiazide
valsartan 4 mg/mL oral solution	Value/Advantage/Cigna Total Savings Drug List Plans: There is documentation the individual has an inability to use the following: A. valsartan tablets Standard/Performance/Legacy Drug List Plans:

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Angiotensin Receptor Blockers are considered medically necessary for continued use when initial criteria are met **AND** there is documentation of beneficial response.

Authorization Duration

Initial approval and reauthorization approval duration: up to 12 months

Background

OVERVIEW

Angiotensin receptor blockers (ARBs) [also known as angiotensin II receptor antagonists] are all indicated for the treatment of adults with hypertension.¹⁻⁸ Some ARBs have other indications as well. Several clinical outcome trials with ARBs have shown positive results. All ARBs, except Edarbi, are also available as combination products with hydrochlorothiazide (HCTZ).⁹⁻¹⁴ Edarbi is available as a combination product containing chlorthalidone (Edarbyclor).¹⁵ There are several products that combine an ARB with amlodipine (plus or minus HCTZ); these products are indicated for the treatment of hypertension.¹⁶⁻¹⁹

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References

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