Effective Date 07/01/2025
Coverage Policy Number 1603

Step Therapy Individual and Family Plan

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Related Coverage Resources

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

Coverage Policy

Individual and Family Plans have a Prescription Drug List that subjects certain brand name drugs to step therapy requiring medical necessity review.

Cigna approves coverage for these drugs as medically necessary when there is a documented failure, inadequate response, contraindication per FDA label, or intolerance to the number of Step 1 and/or Step 2 drugs or as otherwise specified in the table below:

Step Therapy (ST) definitions:

- **Step 1 Medications –** these medications do not require Step Therapy, are automatically covered and do not require prior authorization.
- **Step 2 Medications –** are usually brand name medications. These medications require Step Therapy. If the physician determines the treatment plan should begin with a Step 2 medication, a request for authorization will need to be submitted and approved.

- **Step 3 Medications –** are usually brand name medications. These medications require Step Therapy. If the physician determines the treatment plan should begin with a Step 3 medication, a request for authorization will need to be submitted and approved.

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

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Atypical Antipsychotic *An exception to the criteria will be provided when an individual is not a candidate for (for example, stabilized condition where therapeutic interchange is inappropriate) the step therapy requirements set forth below. (Note: receipt of samples does not satisfy criteria requirements for coverage)* Requires one Step 1 before Step 2	
Step 1	**Step 2**
Aripiprazole Clozapine/ODT Olanzapine/ODT Paliperidone Quetiapine Risperidone/ODT Ziprasidone	Vraylar®
Hypnotic Requires one Step 1 before Step 2	
Step 1	**Step 2**
Eszopiclone Doxepin Ramelteon Zaleplon Zolpidem ER	Belsomra®

Inhaled Corticosteroid (single entity) Requires one Step 1 before Step 2	
Step 1	**Step 2**
Alvesco® Arnuity™ Ellipta® Qvar®	Asmanex® Asmanex® HFA
Insulin, short-acting Requires one Step 1 before Step 2	
Step 1	**Step 2**
Humalog® Cartridge, Kwikpen Humalog® 50-50 Kwikpen, Vial Humalog® 75-25 Kwikpen, Vial	Apidra® Apidra® Solostar Insulin Aspart Pen, Vial Insulin Aspart Pro Mix 70-30 Pen Novolog® Cartridge, Flexpen, Vial Novolog® Mix 70-30 Flexpen, Vial
Long Acting Anticholinergic (COPD) Requires one Step 1 before Step 2	
Step 1	**Step 2**
Incruse® Ellipta®	Tudorza® Pressair®
Long Acting Beta Agonist Requires one Step 1 before Step 2	
Step 1	**Step 2**
Striverdi® Respimat®	Arcapta™ Neohaler™ Serevent® Diskus®

Nasal Steroids Requires three Step 1 before Step 2	
Step 1	**Step 2**
Flunisolide Fluticasone Mometasone	Beconase AQ® Zetonna®
Over Active Bladder (OAB) Requires three Step 1 before Step 2	
Step 1	**Step 2**
Darifenacin ER Fesoterodine Flavoxate Oxybutynin/ER Solifenacin Tolterodine/ER Trospium/ER	Myrbetriq®
Selective serotonin reuptake inhibitor (SSRI), Selective Serotonin-norepinephrine reuptake inhibitor (SSNRI) *An exception to the criteria will be provided when an individual is not a candidate for (for example, stabilized condition where therapeutic interchange is inappropriate) the step therapy requirements set forth below. (Note: receipt of samples does not satisfy criteria requirements for coverage)* Requires three Step 1 before Step 2	
Step 1	**Step 2**
Bupropion/XL/SR Citalopram Desvenlafaxine/ER Duloxetine Escitalopram Fluoxetine Fluvoxamine/ER Mirtazapine/ODT Paroxetine Sertraline Venlafaxine/ER Vilazodone	Fetzima®
Selective serotonin reuptake inhibitor (SSRI), Selective Serotonin-norepinephrine reuptake inhibitor (SSNRI) *An exception to the criteria will be provided when an individual is not a candidate for (for example, stabilized condition where therapeutic interchange is inappropriate) the step therapy requirements set forth below. (Note: receipt of samples does not satisfy criteria requirements for coverage)* Requires one Step 1 before Step 2	
Step 1	**Step 2**
Bupropion/XL/SR Citalopram Desvenlafaxine/ER Duloxetine Escitalopram Fluoxetine Fluvoxamine/ER Mirtazapine/ODT Paroxetine Sertraline Venlafaxine/ER Vilazodone	Trintellix®

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.

Background

Step Therapy is a prior authorization program that encourages the use of less costly yet effective medications before more costly medications are approved for coverage. Health care providers may be able to choose from several different safe and effective prescription medications to treat an individual's condition. Cost is often the biggest difference. Generic medications – which have the same quality, strength, purity and stability as brand name medications – typically cost less, while brand name medications are usually the most expensive.

Step Therapy medications are grouped into two "steps." Though the Step Therapy requirements vary by condition, in general, an individual is required to try at least one Step 1 medication before a Step 2 medication is eligible for coverage without prior authorization.

Drugs included in the Step Therapy program are considered therapeutic alternatives to each other for their respective step therapy group. Therapeutic alternatives (drug protocols with different chemical structures that are the same therapeutic or pharmacological class, and usually can be expected to have similar outcomes and adverse reaction profiles when administered in therapeutically equivalent doses) are determined from FDA approved product information and pharmaceutical compendia sources. Exceptions for indications or uses are noted in the respective clinical criteria above and by specific FDA-approved indication in the table below.

References

1. McEvoy GK, ed. AHFS Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc.
2. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	**Added** Insulin Aspart as an Insulin, short-acting Step 2 product.	03/01/2025
Selected Revision	**Added** Insulin Aspart Pro Mix 70-30 Pen as an Insulin, short-acting Step 2 product.	07/01/2025

The policy effective date is in force until updated or retired.