Coverage Exception

CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	1. The request is NOT for a drug/drug class/medical condition that is restricted to coverage under the medical benefit (Medical Benefit Agents are pharmacy benefit exclusions and non-reviewable; they should be directed to the plan) **AND** **Medical Coverage Table for reference**

Medical devices/supplies (Omnipod is consistent with allowable coverage under the pharmacy benefit), Surgical supplies, Ostomy supplies, IUD's (e.g. Mirena, Skyla, Liletta, Kyleena)
General Anesthetics
Infant formulas (GPI 8110000000****)
Viscosupplements (GPI 758000*)
Vaccines, Toxoids, Passive Immunizing Agents
Medical Benefit Drugs (included on Tier 12)
Jesduvroq (is covered through dialysis bundle)
ROA Exclusions:

CO	COMBINATION
DT	DENTAL
EP	EPIDURAL
HM	HEMODIALYSIS
IL	IMPLANT
IJ	INJECTION (with the exception of Epipen, Adrenaclick, Apidra or other drugs that can be self-administered according to PI)
IA	INTRA-ARTERIAL
IX	INTRA-ARTICULAR
IC	INTRACAVERNOSAL
ID	INTRADERMAL
IM	INTRAMUSCULAR (with the exception of Depo-Testosterone and Makena, Bicillin-LA or other drugs that can be self-administered based on PI)
IO, IZ	INTRAOCULAR
IP	INTRAPERITONEAL
PL	INTRAPLEURAL
IE	INTRASPINAL
IT	INTRATHECAL

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TP	INTRATYMPANIC
IV	INTRAVENOUS (with the exception of Boniva, Stelara, Kanuma, Cinryze, [Hemophilia coagulation factors ARE covered under pharmacy benefit])
VE	INTRAVENTICULAR
IS	INTRAVESICAL
IR	IRRIGATION
PF	PERFUSION
UR	URETHRAL

2. The request is NOT for a compounded medication or Palforzia.If compounded medication contains at least one FDA approved, prescription ingredient or Palforzia send to plan for review. Note: Request not reviewable. Clinician to send to Closure and add a note in comments to instruct to send inquiry letter with the following verbiage: Your request has been forwarded to BCBS Rhode Island. For questions regarding your request, please contact the number on the back of your insurance card. **AND**
3. ONE of the following:
    A. The request is for a drug/drug class/medical condition which is excluded from coverage under the pharmacy benefit and ALL of the following.
        1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process for Coverage Exception **AND**
        2. The patient is currently treated with the requested agent (starting on samples is not approvable) within the past 90 days (claims validation required) **AND**
        3. BOTH of the following:
            A. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose **AND**
            B. The prescribed dose can not be achieved with a lower quantity of a higher strength that does NOT exceed the limit **AND**
        4. ONE of the following:
            A. The request is NOT for an Anorexic, Anti-obesity agent (Third Party Restriction code of 8) AND the patient has received clinical benefit from the requested agent (e.g. stabilization or slowing of disease progression, decrease in symptom severity and/or frequency) (Medical records required) **OR**
            B. The request is for an Anorexic, Anti-obesity agent (third party restriction code of 8) AND BOTH of the following:
                1. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, behavioral modifications, and enrolled in a comprehensive clinically supervised weight loss program (explanation required) **AND**
                2. The patient has achieved weight loss with the requested agent (medical records required)

                If previously approved benefit exclusion criteria is met approve request for 12 months. If criteria is not met deny with benefit exclusion denial **OR**

    B. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit **AND**
    Pharmacy Coverage Exclusion Table for reference

Repackaged products
Alternative medicines (GPI 95*)

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Module	Clinical Criteria for Approval

Anorexic, Anti-obesity agents (Third Party Restriction code of 8)	HIM Plans: Always excluded unless meets exception below All other plans: Excluded unless covered per BET or meets exception below; Exception: Wegovy being used to reduce the risk of major cardiovascular events in patients with known heart disease and with either obesity or overweight
Bulk Chemicals and Pharmaceutical Adjuvants	
Compounding Kits	
Cosmetic drugs (e.g. Botox Cosmetic, Latisse, Restylane, Renova, Avage, Propecia, Vaniqa, Rogaine/Minoxidil, drugs used for a diagnosis of vitiligo and alopecia areata)	
DESI 5 and Desi 6 Drugs	
Diagnostic Agents not on covered drug list (with the exception of diabetic test strips)	
Dietary Management Products (GPI 8125*)	
Disinfectants	
Homeopathic Agents (GPI 9987*)	
Impotence Agents (Note: All PDE5's are a benefit exclusion for Commercial regardless of diagnosis. For HIM, diagnosis of BPH is reviewable and not a benefit exclusion)	
Institutional packs	
Lifestyle drugs (e.g. Vuity, Qlosi)	
Non-FDA approved products (Prime Standard list Included on FID 0220)	
Non-sedating antihistamines (e.g., Allegra, Allegra-D, Clarinex, Clarinex-D, Claritin, Claritin D, loratadine, Semprex-D, Xyzal, Zyrtec, Zyrtec-D)	
Over-the-counter products not on the covered drug list (with the exception of diabetic test strips and insulin) [Infant formulas (GPI-8110000000****) refer to question #2, covered through medical benefit] (Rx-OTC indicator of O or P, unless on the covered drug list or eligible for coverage as part of the Affordable Care Act (ACA))	
Self-Administered Contraceptives (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention)	

4. ONE of the following:
    A. ALL of the following:
        1. The requested agent is in an Affordable Care Act (ACA) Preventative Care category **AND**
        2. The member's benefit includes ACA Preventative Care for the category requested **AND**
        3. ONE of the following:
            A. The requested agent is a contraception agent **AND** ALL of the following:
                1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary **AND**
                2. The requested agent is being used for contraception **AND**
                3. ONE of the following:
                    A. The plan has not implemented a sex requirement **OR**
                    B. The plan has implemented a sex requirement **AND** ONE of the following:

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Module	Clinical Criteria for Approval
	1. The patient's sex is female **OR** 2. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex **OR** B. ALL of the following: 1. ONE of the following: A. The requested agent is in an ACA Preventative Care category **AND** did NOT meet the preventative service requirements **OR** B. ONE of the following: 1. The requested agent is NOT in an ACA Preventative Care category **OR** 2. The member's benefit does NOT include ACA Preventative Care for the category requested **AND** 2. ONE of the following: A. ONE of the following: 1. The request is for a continuity for a behavioral health medication (i.e., Atypical Antipsychotics, Brand Antidepressant, Invega Trinza) **AND** 2. ONE of the following: A. The patient is currently being treated with the requested medication **OR** B. The prescriber states that the patient is currently being treated with the requested agent (including sample use) AND is at risk if therapy is changed **OR** B. ONE of the following: 1. The patient has an FDA labeled indication **AND ALL** of the following: A. ONE of the following: 1. BOTH of the following: A. The requested drug is a drug that is a formulary exclusion but has an interchangeable product that is covered on the formulary (i.e. MSC=O drug, Biosimilars, Human Growth Hormones (all somatropin are interchangeable with each other) **AND** B. ONE of the following: 1. The patient experienced an intolerance to an interchangeable product (e.g. brand drug with a generic equivalent (MSC=O), biosimilars, Human Growth Hormones) that is covered on the formulary and the intolerance is not expected to occur with the requested agent. (ALL of the following must be submitted: date of trial [Rx claims verification required if the date of trial is within the patient's claim history], the specific intolerance(s) and rationale for use of the requested drug) **OR** 2. The prescriber has certified that the patient has been stabilized on the requested medication (Rx claims verification required if the date of trial is within the patient's claim history) and has provided

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Module	Clinical Criteria for Approval
	information that switching could cause harm or health risk to the patient (sample use not allowed) **OR** 2. BOTH of the following: A. A product that has formulary and/or over the counter alternatives for the diagnosis being treated **AND** B. ONE of the following: 1. Patient has tried and failed three formulary (any formulary tier)/OTC alternatives if applicable for the diagnosis being treated with requested drug evidenced by paid claims **OR** 2. A statement by the prescriber listing the three specific formulary alternatives/OTC that the patient has tried and failed **OR** 3. The prescriber provided documentation that available formulary (any formulary tier)/OTC alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient, or has the prescriber stated that the patient is currently receiving the requested medication and is at risk if s/he changes therapy? Current use of samples is not a supportive rationale **OR** 3. A product that does not have a formulary alternative and/or over the counter alternative for the diagnosis being treated **AND** B. If the request is for a drug/drug class/medical condition that is on the list of drugs/drug classes/medical conditions which have additional clinical review criteria (i.e. PA, ST, QL), the patient has met the additional clinical review criteria **AND** C. ONE of the following: 1. Quantity limit does NOT apply to the requested agent **OR** 2. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 4. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limited **AND**

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Module	Clinical Criteria for Approval
	B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **OR** 2. The target agent for an indication that is supported by compendia (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation supported by clinical research in 2 or more peer reviewed medical journals supporting the requested therapeutic use (documentation must be provided and approval by the Clinical Review Pharmacist is required) **AND ALL** of the following: A. ONE of the following: 1. BOTH of the following: A. A product that has formulary and/or over the counter alternatives for the diagnosis being **AND** B. ONE of the following: 1. Patient has tried and failed three formulary (any formulary tier)/OTC alternatives if applicable for the diagnosis being treated with requested drug evidenced by paid claims **OR** 2. A statement by the prescriber listing the three specific formulary alternatives/OTC that the patient has tried and failed **OR** 3. The prescriber provided documentation that available formulary (any formulary tier)/OTC alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient, or has the prescriber stated that the patient is currently receiving the requested medication and is at risk if s/he changes therapy. Current use of samples is not a supportive rationale **OR** 2. A product that does not have a formulary alternative and/or over the counter alternative for the diagnosis being treated **AND** B. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose **AND** C. The prescribed dose be achieved with a lower quantity of a higher strength that does NOT exceed the limit

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Module	Clinical Criteria for Approval
	Length of Approval: ACA Length of Approval: 12 months, Apply $0 copay if ACA criteria met Coverage Exception length of approval: 12 months

CLINICAL CRITERIA OPERATIONAL LEVEL OF EVIDENCE REQUIREMENTS

Module	Ops Set Up	Validation Options	Other Explanation
	Documentation: Requirements as noted within the policy;Validation: Apply Baseline and go to Validation Options	Contraind., intolerance, or hypersensitivity to prereq.;Diagnosis;Other (see Other explanation field)	- The requested agent is covered (not excluded) under the patient's current benefit plan - If the requested agent is a brand product: Availability of a generic equivalent The patient has tried and failed one or more available formulary generic equivalent to the requested agent - If the requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent alternatives Availability of formulary alternatives The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent - The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient - The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent - The prescriber stated that the patient is currently receiving the requested agent and is at risk if the therapy is changed - Additional clinical review criteria has been met

DOCUMENT HISTORY

Approval Date MM/YYYY	Approved By	Notes
-		Client Specific Initial Review criteria, approved by BCBSRI 09/2016 Client Specific Mid-Year Review (revisions to improve efficiencies, clarify QL review) approved by BCBSRI 01/2017 Administrative Action (clarified all PDE5?s are a benefit exclusion for commercial population regardless of diagnosis) 02/2017 Administrative Action (clarified that infant formulas are covered under the medical benefit) 02/2017 Administrative Action (clarified that diabetic test strips are not a benefit exclusion) 03/2017 Administrative Action (clarified diabetic test strips are not a benefit exclusion) 04/2017 Administrative Action (clarification of new to market drugs, ROA exceptions, non-formulary prerequisite requirements) 05/2017 Administrative Action (Billicillin moved to an IM example in table) 06/2017 Administrative Action (addition of new ROA to ROA Exclusion List) 07/17 Client Specific Mid-Year Review (compound medications) 09/2017 Client Specific Custom Criteria Annual Review, without changes, approved by BCBSRI 12/2017 Administrative Action (clarification of Rx-OTC indicator) 01/2018 Client Specific Custom Criteria Annual Review, with changes, approved by BCBSRI 06/2018 Mid-Year Review (streamline criteria, interchangeable product critieria, clarification of PA with QL approval), approved by BCBSRI 08/2018 Administrative Action (clarification of insulin in exclusion table) 09/2018 Client Specific Mid-Year revew (clarification to route generic MSC product through the clinical review process), approved by BCBSRI 10/2018 Mid-Year review (clarification for routing of drugs with no formulary alternatives), approved by BCBSRI 12/2018 Mid-Year Review (clarification for continuation of therapy for short term drugs, clarification of interchangeable product alternatives, infant formula medical coverage), approved by BCBSRI 03/2019 Administrative Action (clarification of intent of guidelines, addition of sample language) Adminitrative Action (addition of Dental ROA, QL clarification language) 04/2019 Mid-Year Review (medical note language, clarification of compendia formulary requirements and interchangeable product language) 05/2019 Client Specific Custom Criteria Annual Review, no changes, approved by BCBSRI 06/2019

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Approval Date MM/YYYY	Approved By	Notes
		Client Specific Custom Criteria Annual Review, with changes, approved by BCBSRI 09/2019 Mid-Year Review (addition of Cinryze in table exclusion, addition of FDA or compendia supported diagnosis. Claridication in compendia section for option d.) approved by BCBCRI 10/2019 Mid-Year Review Client Specific Custom Criteria (defined excluded DESI drugs), 08/2020 Client Specific Custom Criteria, no changes, approved by BCBSRI 01/2021 Mid-Year Client Specifc Custom Criteria, with changes (Omnipod coverage allowable under pharmacy benefit), approved by BCBSRI 04/2021 Administrative Action (OTC option in compendia) 05/2021 Client Specific Annual Review, client specific criteria, with changes, approved by BCBS RI 07/2021 Client Specific Annual Review, client specific criteria, maintained, approved by BCBS RI 10/2021 Admin: added Lifestyle to the pharmacy coverage exclusion table and alphabetized the tables, 2/2022 Admin: fixed typos, 2/2022 Admin: Palforzia addition to routing to plan, 04/2022 Client Specific Annual Review, new format and ACA requirements, approved by BCBSRI 09/2022 Admin: Fixed formularies applied in Ops box 10/2022 Client specific Mid year review, Updated behavior health section, approved by BCBSRI 11/2022 Client Specific Mid year Review, with changes, approved by BCBSRI 02/2023 Client Specific Mid year Review, removal of medwatch requirement 3/2023 Client Specific Mid year Review, addition of Makena to exclusion from medical benefit 05/2023
12-2023	BCBSRI	Annual Review Client Specific Criteria, With changes to criteria
1-2024	BCBSRI	Admin: added Tier 12 medications to Medical Benefit exclusion table, approved by BCBSRI 01/2024
4-2024	BCBSRI	Mid-Year review Client specific criteria, addition of Jesduvroq to medical benefit exclusion table
6-2024	BCBSRI	Mid-Year Review (addition of allowance of weight-loss agents for non weight-loss indications to not be benefit denial)
1-2025	BCBSRI	Administrative Action (addition of QLOSI to benefit exclusion chart)
2-2025	BCBSRI	Administrative Action (addition of weight loss drug benefit exclusion to allow for people whos plan covers weight loss in BET)
2-2025	BCBSRI	Administrative Action (removal of new to market drugs as benefit denial)

NOTES FOR OPERATIONS

CO Notes	Date Created	Last Date ANY Field Changed
- For products restricted to coverage under the medical benefit: Clinician to send to Closure and add a note in comments to instruct to send inquiry letter with the following verbiage: You are requesting a drug that is restricted to coverage under your medical policy. For questions regarding coverage limitations under your benefit plan, please contact a service representative by calling (800) 639-2227. - For requests for compounds or Palforzia: Send to Plan for review. Clinician to send to Closure and add a note in comments to instruct to send inquiry letter with the following verbiage: You are requesting a drug that is restricted to coverage under your medical policy. For questions regarding coverage limitations under your benefit plan, please contact a service representative by calling (800) 639-2227 - The plan has not implemented a sex requirement for contraceptive requirement - For behavior health question. Please accept attestation at the risk with change and COT - There are TWO FAXES that need to be made for this program Contraceptive fax and Coverage Exception For criteria team CMM RI CE Build Questions: #3 Is the Benefit Class BCBSRI Comm FI Grp or BCBSRI HIM FI Grp? Yes > (a new number 4) No > Continue to the new #5 (current #3 - Is the request for a drug coverage that is:) #4 Is the classification 1st Level Appeal Specialist? Yes > Continue to the new #5 (current #3 - Is the request for a drug coverage that is:) No > Other box: Send to Research to change the classification to appeal for Fully Insured/HIM CE CORE RI CE Questions: #3 Is the Client Name BCBSRI FI or BCBSRI HIM? Yes > (a new number 4) No > Continue to the new #5 (current #3 - Is the request for a drug coverage that is:) #4 Is the classification First Level Appeal? Yes > Continue to the new #5 (current #3 - Is the request for a drug coverage that is:) No > Other box: Return to Tech to change the classification to appeal for Fully Insured/HIM CE For drug/drug class/medical conditions that are excluded but previously approved through CE criteria, if current treatment, appropriate dosing, OR clinical benefit	04-02-2025 04:33:14 PM	

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CO Notes	Date Created	Last Date ANY Field Changed
requirements are not met, deny with product not covered under pharmacy benefit denial reason BCBSRI does not accept the use of samples to satisfy prerequisite requirements in any of the step therapy or prior authorization programs. Samples would also include any type of prescription or copay assistance rendered to the patient by the drug manufacturer or any other organization that would allow the patient to get the drug without a paid claim through billing BCBSRI		

POLICY REVIEW CYCLE

Effective Date	Date of Origin	Status
04-23-2025		Draft

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