Title:	Coverage Determinations - Exceptions	**Effective Date:**	4/13/2021
Category:	Department	**Approved Date:**	4/12/2021
Line of Business:	☑ Commercial ☑ Exchange ☑ Managed Medicaid	**Review Due Date:**	4/9/2022
Accreditation(s)/ Other Program(s):	☑ NCQA ☑ URAC	**Owner:**	Christopher M. LeClair
		Approved by:	Mohan S.K. Yellepeddi

Purpose:

The purpose of this policy is to standardize the process for responding to requests for exceptions to benefit or coverage limitations and outline the criteria by which requests are reviewed. Drug-specific benefit limitations are established as utilization management tools. It is recognized, however, based on medical necessity, that certain circumstances may warrant granting an exception for certain members. A coverage exception request is made prior to a formal denial process such as grievance or appeal. Benefit limitations for which exceptions to coverage are requested include coverage for drugs not normally covered due to:

- Non-covered formulary status*;
- Plan exclusions established by the client*;
- Non-covered form of a formulary drug (such as injectable or patch)*;
- Step therapy requirements when the patient profile does not meet Step Therapy criteria;
- Quantity limit restrictions when the prescribed quantity exceeds the established limit;
- Self-injected drug normally administered in a clinic setting and covered by medical benefit*;
- Use of gender-specific medications in non-standard gender;
- Pre-formulary review status*;
- Coverage outside of existing criteria for prior authorization;
- Clinical concurrent drug utilization review (CDUR) rejects.

* Excludes Texas Medicaid CHIP/STAR. Drug must be covered on the VDP formulary.

Policy:

Navitus will establish and maintain policies for tracking and addressing timely review and resolution of exception requests for coverage. Navitus will ensure all client, state, federal, or accrediting body requirements are complied with and utilize this body for the basis of the utilization management program when these other bodies do not require unique processes. Client-specific processes will be maintained in staff work instructions.

A Navitus clinical pharmacist reviews all coverage exception requests and bases the coverage determination on information available at the time of review which may include one or more of the following:

- Peer-reviewed medical literature including randomized clinical trials, pharmacoeconomic studies and outcomes research data;
- Pre-established criteria;
- Application of published practice guidelines from an acceptable evidence-based process;
- Current clinical processes and principles;
- Collaboration with physicians familiar with the medication and/or therapy;
- Consideration of the member's applicable medical records e.g. relevant labs, allergies, past medications failed to treat the condition, etc and other individual health care needs e.g. psychosocial information and home environment when applicable;
- Evaluation of the benefits, risks and potential outcomes with alternative therapies;
- Knowledge of the local delivery system.

Navitus will ensure:

- Coverage determination clinical review employees are pharmacists with an active, professional, relevant license in good standing as required by law and follow established review criteria. Navitus pharmacists may choose to consult with experts in the field (e.g. Board Certified Practitioners) for assistance in requests (see appendix 1)
- All denials (non-certifications) are determined by a pharmacist or appropriate physician. All rationale for denial and redirection to other formulary alternatives will be determined by the same and based on the member's personal health information available at the time of the determination compared against the clinical criteria for approval. E.g: diagnosis and any formulary alternatives.

All formulary benefit limitations, as well as the criteria by which exception requests are reviewed, are evaluated and approved by Navitus' P&T Committee at least annually. Any additions, changes or modifications to exception review criteria and/or this policy will be reviewed and approved by the Formulary Advisory Committee (FAC) and captured in minutes.

Procedures:

1. The prescriber or member, as applicable, submits an exception request indicating use of formulary alternatives and/or supplying supporting chart documentation to indicate the need for an exception.
2. When the request is received by Navitus, the pharmacist or physician reviews the information available.
3. The Navitus pharmacist may seek assistance from physicians and other specialty physicians.

   Navitus will document utilization of such consultants as part of the episode within the electronic record.

   a. Documentation includes the pharmacist name, the episode number, the physician specialty, the date of the request and the response date. The document is kept in Compass/Health Strategies/Pharmacist Resources/Policies and Procedures/Specialist Outreach NCQA Document.
4. Navitus limits the scope of review as follows:
   a. Acceptance of information from an evidence-based process to assist in the exception review process;
   b. Navitus only collects information necessary to review requests;
   c. Prescriber and member confidentiality are maintained as required by HIPAA at all points during the process;
   d. Navitus requires only the applicable portion of medical records necessary to determine appropriateness of the exception request.
5. An exception to coverage will be allowed if at least one of the following criteria is met:
   a. Brand only requests submitted with a completed FDA MedWatch form. Prescribers should submit an FDA MedWatch Form to the FDA and Navitus. Forms may be accessed at: FORM FDA 3500; or
   b. The member has had an adequate trial of formulary alternatives as determined by the clinical pharmacist reviewer; or
   c. The provider attests the requested drug is medically required for an FDA-approved indication and other formulary drugs may be less effective or less safe for the member because they all either:
      1) Have been ineffective in the treatment of the disease or medical condition or
      2) Are likely to be ineffective or adversely affect the drug's effectiveness or patient compliance based on the known relevant physical or mental characteristics of the member, both sound clinical evidence and medical and scientific evidence, and known characteristics of the drug regimen; or
      3) Have caused or, based on sound clinical evidence and medical/scientific evidence, are likely to cause an adverse reaction or harm to the member.
   d. The drug is requested for an off-label indication and both points below are satisfied:
      1) The indication is accepted for treatment by virtue of

a) Accepted for off-label use in a commonly referenced compendia (see *Clinical Decision Support Tools* policy and procedure for listing) and/or;

b) Having been shown to be statistically significantly superior to approved treatment(s) in at least one controlled, randomized clinical trial that is published in the peer-reviewed medical literature. To demonstrate provider familiarity with the treatment regimen requested, the requester of the exception must supply this literature.

2) Other formulary drugs are less effective or safe because they all either:

a) Have been ineffective in the treatment of the disease or medical condition or

b) Are likely to be ineffective or adversely affect the drug's effectiveness or patient compliance based on the known relevant physical or mental characteristics of the member, both sound clinical evidence and medical and scientific evidence, and known characteristics of the drug regimen; and/or

c) Have caused or, based on sound clinical evidence and medical and scientific evidence, are likely to cause an adverse reaction or other harm to the enrollee.

e. The requested drug triggers a clinical CDUR edit and is accompanied by adequate clinical rationale.

f. For Texas Medicaid STAR/CHIP, the drug is a covered product. All exceptions for not covered or excluded products must be reviewed and approved by the MCO.

g. For California clients governed by DMHC, if a medication has previously been approved for a member's medical condition, Navitus will continue to approve coverage of that medication, even if the medication is no longer on the formulary, as long as the medication is considered safe and effective for treating the enrollee's medical condition.

1) This does not apply to a medication that has been previously prescribed for a medical condition of a limited timeframe, and then discontinued.

6. An exception to coverage may be denied for the the following reasons:

a. Coverage of gender-specific medications will not be approved for gender reassignment, gender identity disorder or libido if excluded by the plan;

b. Coverage for infertility when excluded by the plans;

c. Non-allergy related brand-name only requests unaccompanied by an FDA MedWatch form;

d. Non-formulary medications prescribed as a continuation of therapy started by prescription drug samples or drug coverage from a previous health plan unless required by the client or law/regulation;

7. If approved:

a. Exchange/Marketplace:

1) An exception request based on exigent circumstances provides coverage of the non-formulary drug for the duration of the exigency.

2) An exception request based on standard circumstances provides coverage of the non-formulary drug for the duration of the prescription, including refills.

3) Excepted drugs are treated as an Essential Health Benefit (EHB), including by counting any cost-sharing twoards the Plan's annual limitation on cost-sharing under 45 CFR 156.130.

b. Commercial/Medicaid:

1) Exception requests are granted for one year or until the end of the member's active eligibility with the client, whichever is less. Requests triggering a clinical CDUR edit may be approved for lifetime if accompanied by adequate clinical rationale.

2) For clients governed by DMHC, exception requests may be granted coverage for longer than one year if deemed medically necessary and appropriate for coverage to be longer than one year.

a) Exception requests may be approved for a lesser duration based on requests for medications which are indicated to be used for a limited timeframe.

8. Copay (Tier) lowering requests may reduce the copay by ONE level from non-preferred to preferred tier if one of the following are met:

a. Trial of all formulary therapeutic alternatives

b. Copay lowering requests without failure of all therapeutic alternatives and/or one of the following criteria:

1) Generally accepted medical practice not supporting the use of formulary preferred medications indicated for a specific disease state.

2) Existence of known drug to drug interactions between Preferred alternatives and a requested Non-preferred medication

c. Medications INELIGIBLE for tier lowering include:

1) Medications on a specialty tier

2) Medications approved through a formulary exception to coverage process

3) Medications currently covered on a Preferred tier

9. If denied, the member is notified of applicable appeal options available to them:

a. Plan level appeal information is provided to the member and/or prescriber;

b. For products specifically excluded from coverage by the plan sponsor, coverage is not normally granted but requests are always reviewed;

c. In some cases, the product may be covered through the member's medical benefit and can be referred to their medical plan;

d. The member and/or prescriber may be notified that the member can fill the prescription but will be responsible for the full cost of the prescription.

e. For Exchange/Marketplace, members can request that the denied exception request be reviewed by an independent review organization.

10. A decision will be rendered within:

    a. Non-Urgent and Urgent Commercial: The regulatory requirement is to render a decision within five (5) days of receipt by Navitus or sooner if required by client contractual, state, or federal requirements. The standard Navitus process is to render a decision within two (2) days of receipt. For CA clients governed by DMHC, 72 hours (standard) or 24 hours (expedited) after request is received.

    b. Non-Urgent and Urgent Medicaid: As required by state law, generally one business day or 24 hours of receipt by Navitus. For CA clients governed by DMHC, 24 hours after request is received.

    c. Standard and Expedited Exchange/Marketplace: 72 hours (standard) or 24 hours (expedited) after request is received.

    d. If all required information is not received, the prescriber will be notified of the additional information needed.

11. All coverage decision notification letters include information required to track the request (patient name, drug, date) and:

    a. Contact information for questions regarding the decision.

    b. All denials will include:

        1) Principal reasons for the decision not to certify/approve in easily understood language;

        2) A clear statement of the clinical rationale used in making the decision or a statement indicating the process by which to request the clinical rationale used in making the denial decision and how to request such information;

        3) All denial notifications will include an explanation of the member's rights, the appeal process including instruction on initiating an appeal, the right to submit written comments, documents or other information relevant to the appeal and appeal contact information, timeframes, and right to representation.

        4) When applicable, a reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based.

        5) A statement that members can obtain a copy of the actual benefit provision, guideline, protocol or other similar criterion on which the denial decision was based, upon request.

        6) Contact information if the provider wants to speak with a reviewer.

12. Notifications of the decision rendered will be:

    a. Commercial/Exchange:

        1) Non-urgent approval and denial: mailed to the member within two (2) business days of the decision. For CA clients governed by DMHC, the

decision and the initiation of the member and provider notification is completed within 72 hours after the request was received.

2) Urgent Approval and Denial: mailed to member within 1 business day. For CA clients governed by DMHC, the decision and initiation of the member and provider notification is completed within 24 hours after the request was received.

3) Prescriber notifications: Prescribers are faxed notifications within 24 hours of the decision.

4) Other as required by client (state, federal, accreditation) regulations. Specific turnaround times by client are maintained in staff work instructions.

b. Non-Urgent and Urgent Medicaid: Mailed notifications within one business day. Faxed notifications within 24 hours. For CA clients governed by DMHC, the decision and initiation of the member and provider notification is completed within 24 hours after the request was received.

13. A coverage exception approval of a prescription drug claim based on medical necessity, appropriateness, level of care, or effectiveness will not be reversed by Navitus unless:
    a. Credible new information is received relevant to the certification not available at the time of the original certification;
    b. A client instructs Navitus to do so;
    c. Evidence of fraud is discovered in the documentation supporting the original certification.
14. Exception to coverage requests may be audited quarterly. Results will be presented to the Clinical Quality Team and Quality Management Committee at least annually.

Area(s) of Responsibility:

Department: Clinical Prior Authorization
Owner: Supervisor, Clinical Prior Authorization

Regulatory/Requirement References

☒CFR: 45 CFR § 156.130

☐CMS Prescription Drug Benefit Manual

☐CMS

☐HPMS Memo

☐State Contract

☒State Law: Knox-Keene Act: 1367.22 – 1367.24

☐State Regulatory Guidance

☒Other

URAC: DrUM 1b.iii, c; 2a-d; 3a-d, 4a,b, d, h, j,k, o; 7; 8a-c; 9; 14a-c; 15;16a-c; 17a; 18a-b; PTFD 9; PTFD 11

NCQA: UM-2 A.3; UM-4 F.1; UM-7 G; UM-11 A 1-2; D.1-4; E.1-5

Appendix 1: Appropriate Professionals in Medical Review

Level	Staff	Licensure	Consultation Required
Administration Review	• Clinical Prior Authorization Specialists • Prior Authorization Specialists	• None required • LPN • Certified Pharmacy Technician	No
Clinical Review 1st level (PA)	• Clinical Pharmacist • Medical Director	• Licensed Pharmacist • Licensed Physician • All pharmacists and physicians have a current license to practice without restriction	No
Clinical Review 2nd level (Appeals)	• Clinical Appeals Pharmacist • Medical Director	• Licensed Pharmacist • Licensed Physician • All pharmacists and physicians have a current license to practice without restriction	NCQA clients: Yes (Specialty must match case) Non-NCQA clients: No