Table of Contents:

- **Formulary Transition Policy**
    - **Policy**
    - **Formulary (Clinical) Transition for New Members**
    - **Formulary Transition (Change) for Current Members**
    - **Definitions**

PHARMACY INFORMATION

Navitus Part D Formulary Administration

Purpose:

Navitus Health Solutions (NHS) manages formularies for Liberty Medicare Advantage Part D Plan. This process demonstrates how Navitus implements and maintains Medicare Part D formularies as needed to comply with the Center for Medicare and Medicaid Services (CMS) Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements.

Policy:

Navitus is responsible for making appropriate coverage decisions and ensuring that covered Part D drugs and managed Part D formularies meet the requirements in Chapter 6 – Part D Drugs and Formulary Requirements of the Medicare Prescription Drug Benefit Manual.

Part D drugs are defined in Title XVIII of the Social Security Act (the Act) and in regulations (42 CFR 423.100). Subject to exclusions, a Part D drug means a drug that may only be dispensed with a prescription, is being used for a medically accepted indication as defined by section 1927(k)(6) of the Act, and is one of the following:

• A drug that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;

• A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;

• Insulin described in section 1927(k)(2)(C) of the Act;

• Medical supplies associated with the delivery of insulin; or

• A vaccine licensed under section 351 of the Public Health Service Act and its administration.

Part D specifies that a drug prescribed to a Part D eligible individual cannot be considered a covered Part D drug if payment for such drug "...is available (or would be available but for the application of a deductible) under Part A or B for that individual."

If payment could be available under Part A or Part B to the individual for such drug, then it will not be covered under Part D. Consequently, drugs covered under Parts A and B are considered available (and excluded from Part D) if a beneficiary chooses not to pay premiums or if a beneficiary has enrolled in Part B but that coverage has not yet taken effect.

In accordance with section 1860D-2(e)(3) of the Act, Navitus may exclude from qualified prescription drug coverage any Part D drug

- For which payment would not be made if items and services are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (except for Part D vaccines); or
- Which is not prescribed in accordance with the Part D sponsor.

Such exclusions are coverage determinations subject to reconsideration and appeal. Unlike other Part D drugs that may be excluded when not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Part D vaccines may only be excluded when their administration is not reasonable and necessary for the prevention of illness.

Part D drugs do not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2) of the Act, except for smoking cessation agents.

Navitus may include coverage of drugs that would meet the definition of a Part D drug as a supplemental benefit under enhanced alternative coverage.

Part D formularies must include drug categories and classes that cover disease states consistent with Part D program requirements. Part D sponsors may use existing classification systems or create their own. CMS will evaluate the sufficiency of a Part D sponsor's formulary categories and classes in conjunction with the formulary drug list to ensure that the formulary provides access to an acceptable range of Part D drug choices.

Each category or class must include at least two drugs (unless only one drug is available for a particular category or class, or only two drugs are available, but one drug is clinically superior to the other for a particular category or class), regardless of the

classification system that is utilized. The two-drug minimum requirement must be met through the provision of two chemically distinct drugs. Aside from the inclusion of two drugs in each category or class, multiple strengths and dosage forms should also be available for each covered drug. This should encompass dosage forms used commonly in long term care (LTC) facilities and home infusion.

CMS may require more than two drugs for categories or classes if additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the Plan Sponsor's formulary would substantially discourage enrollment by beneficiaries with certain disease states.

Navitus provides medically necessary prescription drug treatments in accordance with the two drug requirements for enrollees in the general Medicare population, as well as those enrollees who reside in LTC facilities. When determining days supplies for residents in LTC facilities, Navitus follows industry best practices and allows for at least 31 days per fill.

42 CFR 423.578(a)(7) allows Navitus to exempt a formulary tier, in which it places very high cost and unique items, from tiered cost-sharing exceptions. Cost-sharing associated with the specialty tier is limited to 25% after the deductible and before the initial coverage limit (or an actuarially equivalent for sponsors with decreased or no deductible under alternative prescription drug coverage designs).

In response to CMS inquiry regarding Medication-Assisted Treatment (MAT) coverage, Navitus ensures accessibility for MAT options for opioid abuse or overdose.

Navitus formularies must also include all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes.

Formularies must include substantially all drugs in these six categories that are FDA approved by the last CMS-specified Health Plan Management System (HPMS) formulary upload date for the upcoming contract year. Medications in protected classes and with orphan status are added to the formulary with appropriate clinical or utilization edits after NHS review of the initial CMS Formulary Reference File (FRF).

New drugs or newly approved uses for drugs within the six classes that come onto the market after the CMS-specified formulary upload date will be subject to an expedited Pharmacy and Therapeutics (P&T) committee review. The expedited review process requires P&T committees to decide within 90 days, rather than the normal 180-day requirement. At the end of the 90-day period, these drugs must be added to Part D formularies.

Navitus reviews all new molecular entities, new drug formulations and FDA indication updates during monthly Formulary Advisory Committee (FAC) meetings and/or quarterly P&T meetings. Protected class drugs are reviewed by committee(s) within the CMS required 90 days. Navitus coverage decisions following the review of each FRF are informed by committee outcomes. If a protected class drug has not been reviewed by committee prior to its addition to the FRF, Navitus will make a coverage determination that maintains formulary compliance with CMS substantially all rules. Coverage is adjusted as necessary to account for protected class drug deletions from the FRF.

Coverage decisions are provided to Liberty Medicare Advantage (LMA) following the review of each FRF. LMA is required to return sign off on all coverage decisions; LMA is required to specify coverage in the event they reject a Navitus recommendation.

Formulary Operations will enter coverage decisions in the Formulary and Benefit Management System (FBMS) system for the creation of CMS submission files. NHS NaviClaim Rx (NCRx) files are created in FBMS or RXFlex, depending on the client. Submission files are based on RxCUI-related National Drug Codes (NDCs) and submitted to CMS. NCRx files are generic product indicator (GPI)-based and sent to the Benefits Configurations Analysts (BCA) department to be set up in the NCRx adjudication system. These files are compared monthly to ensure the CMS submission file and the NCRx formulary file contain the same information.

All other enhancements or negative changes to any Navitus managed Medicare Part D formularies must come from Liberty Medicare Advantage, be approved by a Navitus clinical committee, or be mandated by CMS. For negative changes, NHS must also inform CMS and plan participants prior to implementing the negative change. Changes are submitted during the next appropriate submission cycle.

Formulary documents, including Formulary Drug Lists, Step Therapy requirements, and Prior Authorization requirements are printed monthly using the formulary files and distributed to clients and/or posted to the appropriate web portals.

Part D sponsors that fail to meet formulary submission and re-submission deadlines during the formulary approval process may face a CMS determination that CMS cannot approve their Part D bids. For most Part D sponsors, a failure to obtain bid approvals will result in the termination of their Part D sponsor or MA organization contracts effective at the end of the existing contract year. In the case of an initial Part D sponsor or MA organization contract applicant, CMS would decline to enter a contract with the organization.

All Part D sponsors that fail to meet CMS established formulary timelines will be precluded from entering a contract with CMS. Such a determination would be made on the basis that the organization had failed to submit a bid which CMS could approve, a

determination that would not be subject to a request for appeal under Subpart N of 42 CFR 423 (for Part D sponsors) and 42 CFR 422 (for MA organizations). Clients are responsible for meeting all Navitus deadlines, which are set to provide ample time to review prior to submission.

Prior Authorization Coverage Determinations

The adjudication timeframe, notice, and other requirements applicable to coverage determinations under part 423, subpart M of the Medicare Part D regulations apply to requests that involve a PA or other utilization management (UM) requirement in the same manner they apply to all coverage determinations.

- Upon receipt of a prior authorization coverage determination request, the pre-established criteria is reviewed against the information submitted.
- If the request is for a protected class drug, every effort will be made to understand prior utilization of the requested medication including review of available paid claims history.
    - If there is evidence of established therapy (in the previous 180 days), approval will be granted.
    - If there is not at least 108 days of claims history/eligibility available, efforts will be made to
    - determine whether therapy has been established. If this information is obtained or available, approval will be granted.
    - If the request clearly meets the CMS approved criteria, the Specialist will process the request and complete the effectuation.
    - If the request does not clearly meet the CMS approved criteria, the request is forwarded for pharmacist review.

- If all information required to approve the request is not provided, the requestor will be notified of the specific information needed.
    - Additional information can be supplied in oral or written form. If PA criteria require supplemental documentation to be provided, oral information will not be accepted.
    - All determinations will be made within the required timeframes regardless of whether additional information is received.

- For expedited and standard requests, the provider will be notified via fax to request the information needed to approve the request.
- The outreach attempt is made after the clinical pharmacist's initial review of request.
- All outreach attempts will be documented as part of the record.

- Determinations will be rendered, and the notifications provided no later than:
  - Expedited: 24 hours from the time of the request
  - Standard: 72 hours from the time of the request

Exceptions

When evaluating a coverage determination, a Navitus pharmacist is responsible for determining whether the request is an exception or not. The following types of requests would be classified as exceptions:

- Request to obtain a drug in a higher cost -sharing tier at a more favorable cost-sharing tier (tiering exception).
- Request for a quantity of medication that exceeds the quantity limit submitted to and approved by CMS (quantity limit exception). Request for a medication that is not on the CMS-approved formulary (non-formulary exception).
- Request to bypass one or more prior authorization requirements submitted to and approved by CMS (prior authorization exception).
- Request to bypass the step therapy requirement(s) submitted to and approved by CMS (step
- therapy exception).
- Request to bypass opioid safety edits

- Specifically, regarding prior authorization and step therapy coverage determinations:
  - Navitus will only classify these requests as exceptions when documentation clearly indicates that the beneficiary, authorized representative, or provider is asking for a waiver of one or more of the CMS-approved utilization management criteria.

- Additionally, if the submitted diagnosis is outside of the approved utilization management criteria (for example, non-FDA labeled indication), the request will be classified as an exception unless otherwise determined by Navitus clinical staff
- Finally, if upon outreach and subsequent receipt of additional information and/or a supporting statement the classification of the request changes, the reported request type will remain as previously categorized prior to outreach, if changing the request type would impact the original turnaround time. Request type may be updated if the allowable timeframe is not impacted.
- For example, if (based on initial documentation) the request is determined to be a prior authorization exception, sent for outreach, and additional information is received indicating that the request would subsequently be classified as a prior authorization (non-exception), the request type would continue to be identified as a prior authorization exception, since changing the request type after tolling would be outside the allowable timeframe.
- This process is to ensure that a decision is rendered within the allowable timeframes based on the documentation that was available to the reviewer at the time of original classification.

Tiering Exception

Navitus pharmacists review tiering exception requests according to the guidance provided in Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

1) Requests will be processed according to timeframes and outreach requirements as previously outlined in Prior Authorization Coverage Determinations (below).
   - If the supporting statement is not received, Navitus will toll the request for 14 calendar days from receipt of the request. The notification will be sent on or immediately following the 14th day, not to exceed 72 hours (standard) or 24 hours (urgent) passed the decision date.
   - Additional information and supporting statements can be supplied in oral or written form.
   - An approval will be granted when submitted information supports medical necessity criteria
   - indicated above.

- A denial will be rendered when supporting information is not supplied upon request and/or if all information supplied within the required timeframe fails to indicate medical necessity criteria indicated above.
- Navitus decisions regarding a tiering exception requests will not be based solely on the label of the tier containing alternative drugs, rather what types of drugs (brand or generics/authorized generics) are included in the individual tiers.
- For the purposes of Tiering Exceptions, authorized generics are treated as generics.
- Navitus will limit the availability of tiering exceptions for:
    - A brand name drug or biological product at the cost sharing level of alternative drugs, where the alternatives include only generic or authorized generic drugs. Specialty drugs at a specialty tier will not be eligible for tiering exception
    - A non-formulary drug which was approved under the formulary exception process
    - A brand drug when requested at a generic cost sharing tier if the plan sponsor maintains a formulary with separate and distinct tiers for brands and generics.
    - A drug that is already at the lowest cost sharing tier or if the plan sponsor maintains a formulary with only one tier/cost sharing is the same for all formulary tiers.

- Navitus will grant a tiering exception when:
    - A supporting statement (as outlined in Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance) is received that establishes medical necessity and does not meet one of the scenarios listed above.
    - Approvals will apply cost-sharing to the lowest applicable cost-sharing tier that contains alternatives for the requested drug.

Formulary Exceptions – Appeals, Grievances and Organizational/Coverage Determinations

Liberty Medicare Advantage uses Navitus as our Part D vendor. At Navitus, their goal is to make each member's pharmacy benefit experience seamless and accurate. However, there are rare occasions where that experience may fall short. When this happens, they do their best to make it right.

What do I do if I believe there has been a pharmacy benefit processing error?
Start with the Customer Care number listed on the card you use for your pharmacy benefits. Customer Care can investigate your pharmacy benefits and review the issue. Most issues can be explained or resolved on the first call.

What does Navitus do if there is a benefit error?
They make it right. If there is an error on a drug list or formulary, you will be given a grace period to switch drugs. If you have been overcharged for a medication, we will issue a refund. Typically, Navitus sends checks with only your name to protect your personal health information (PHI).

What are my Rights and Responsibilities as a Navitus member?
Your rights and responsibilities can be found at navitus.com/members/member-rights.

What if I have further concerns?
If you have a concern about a benefit, claim or other service, please call Customer Care at the number listed on the card you use for your pharmacy benefits. If you wish to file a formal complaint, you can also mail or fax:

Address:	Navitus Health Solutions Attn: Grievance and Appeals Department PO Box 999 Appleton, WI 54912-0999
Toll-Free	855-673-6507
Fax:	Attn: Grievance and Appeals Department

Upon receipt of a formulary exception request, a Navitus pharmacist will determine if a supporting statement has been received and meets the standards defined in Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

- Requests will be processed according to timeframes and outreach requirements as previously outlined in Prior Authorization Coverage Determinations (above).

- If the supporting statement is not received, Navitus will toll the request for 14 calendar days from receipt of the request. The notification will be sent on or immediately following the 14th day, not to exceed 72 hours (standard) or 24 hours (urgent) passed the decision date.
- Additional information and supporting statements can be supplied in oral or written form.
- If the supporting statement is received, but further information is necessary, Navitus will perform one outreach attempt via fax to the provider's office to obtain that information. If the additional information is not received prior to TAT (24 hours for expedited, 72 hours for standard) the case will be closed based off the supporting statement information.
- An approval will be granted when submitted information supports medical necessity criteria as outlined in Parts C & D Enrollee Grievances, Organization/ Coverage Determinations, and Appeals Guidance.
- A Quantity Limit will not be applied to formulary exception approvals, unless there is a maximum daily dose limit that is clearly established by the FDA for patient safety reasons.
- A denial will be rendered when supporting information is not supplied upon request and/or if all information supplied within the required timeframe fails to meet medical necessity criteria outlined in Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

General Coverage Determination Processes

- If Navitus receives a coverage determination marked as expedited or any verbiage implying the same, the request will automatically be processed according to the expedited Timeframe. The expedited Timeframe does not begin until the Medicare UM Department at Navitus receives the request.
- If a coverage determination request is received without indication that the requesting party is requesting expedited processing, Navitus processes the request under the standard Timeframe without first applying established accepted standards of medical practice in assessing an individual's medical condition to determine the urgency of the coverage request and subsequently prioritize the request according to these standards.
- If a member, provider, or appointed representative indicates orally or in writing that they no longer want to proceed with an active coverage determination they requested it will be considered withdrawal. The withdrawn notification will be issued as outlined in the Written Notifications section of this policy (below).

- If Navitus receives a coverage determination request from an entity other than the enrollee or prescriber, Navitus must first attempt to obtain the CMS 1696 form or an equivalent written notice as defined by CMS (20.2 – Appointment of Representative (AOR) Form or Equivalent Written Notice), or other legal or court issued papers to verify the requestor is the enrollee's appointed representative.
    - To avoid delays in reviewing a case in instances where Navitus does not have the CMS1696 form or an equivalent written notice as defined by CMS (20.2 – Appointment of Representative (AOR) Form or Equivalent Written Notice), or other legal or court issued papers to verify enrollee appointed representative, Navitus will reach out to the prescriber to see if they are willing to initiate the request.
    - If the prescriber is willing to initiate the request, Navitus will use the prescriber initiation date/time as the received date/time.
    - To avoid member confusion, Navitus will not issue a dismissal in these instances and will continue with the original Coverage Determination.
    - Navitus will keep all the notes from the initial request, outreach to prescriber and subsequent decisions/notifications in one case file.
    - If the prescriber is not willing to initiate the request or If Navitus cannot obtain the CMS 1696 form, or an equivalent written notice as defined by CMS (20.2 – Appointment of Representative (AOR) Form or Equivalent Written Notice), other legal or court issued papers and establish they are an appointed representative for the enrollee within 5 business days, the request will be dismissed and the enrollee and submitter will receive written notification of the dismissal.
    - Subsequent coverage determination requests submitted within 60 days of the denial of the initial coverage determination will be processed as a redetermination.

<u>Notification of Determinations</u>

- **Written Notifications:**
    - Written notice of all decisions will be sent to the enrollee within the established TAT. The written notification will be placed in a courier drop box within the CMS defined TAT to ensure timeliness of written notification as defined by 10.5.3 of the CMS Prescription Drug Benefit Manual - Parts C & D
    - Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance

- If an enrollee has identified a representative with the request, the written notice will be mailed to the enrollee's representative instead of the enrollee.
- Each letter is inserted into an envelope and run through a postage machine. The postage machine date stamps the letter.
- The front of the envelope is scanned and a copy of the PDF image is saved to a folder on a network drive. Each envelope results in its own unique document. At the time of scanning , each letter is logged by last name, first initial that can be used for audit purposes. The scanned envelope images are stored by date the case was resolved (date the letter was generated).
- All coverage determinations closed prior to 3:00PM CST Monday through Friday will be picked up by the mail courier at 4:00PM CST. All coverage determinations closed after 3:00PM Monday through Friday or over the weekend and/or on a Holiday, will be picked up by the courier on the following business day at 4:00PM CST.
- Any requests were TAT falls outside of the 4:00PM CST pick-up time will be placed in a courier drop box before TAT expires to ensure timeliness of notification.
- Daily, a report is generated to ensure that a letter was printed/mailed for each case that was resolved the day before. The report identifies the requests that were closed and compares against the log created at the time of scanning. In the event of a d discrepancy, the supervisor is notified immediately, and a letter is generated and mailed immediately.

Denial Notifications:

- The CMS model denial notice will be used, and written denial notifications will provide:
  - OMB-approved specific language for Part B vs. Part D denials found in standardized denial notice
  - Criteria used for denial, including any formulary criteria used (including formulation and strength as appropriate), compendia or FDA recommendations used in decision, and Medicare or CMS-approved plan coverage criteria used.

- For exceptions, if a supporting statement is not obtained from the prescriber, the denial notice to the enrollee must clearly explain that the request was denied due to a lack of medical necessity and that the prescriber did not produce the necessary supporting statement.

- All denial language will be using predefined templates based on the guidelines outlined
- above and customized by the clinical reviewer.
- Denial reasons will be included within the denial notifications include the following: not medically necessary, ineligible Benefit requested, Medicare D excluded drug, Medicare
- Part B Benefit, and plan exclusion.
- Contact information for the provider to discuss denial decisions.
- Information regarding the right to appoint a representative to file an appeal on the enrollee's behalf;
    - A description of appeal rights including the right to submit information relevant to the appeal in a culturally and linguistically appropriate manner.
    - A description of both the standard and expedited redetermination (expedited not applicable for payment denials) processes and time frames, including conditions for obtaining an expedited reconsideration, and the rest of the appeals process.
- **Approval Notifications:**
    - Approvals must indicate the date the coverage approval will expire.
- **Withdrawal Notifications:**
    - Notifications are issued to both the member and prescriber indicating the case has been dismissed and no further review will occur at that time.
- **Dismissal Notifications:**
    - Notifications are issued to both the requestor and the member when an unauthorized representative submits a coverage determination and Navitus is unable to obtain the necessary documents to review the request.
    - Notifications are issued to both the member and prescriber when an Exception to Coverage request has been approved and Tier Lowering is being requested.
- **Prescriber Notifications:**
    - Prescribers will be notified via fax of all coverage determinations within 1 business day of the decision.

Implementing Favorable Decisions:

- **Duration:**
    - Standard prior authorizations will be approved for one year unless clinically inappropriate or unless a different duration has been established via the CMS approved criteria.
    - Standard step therapy and step therapy exception requests will be approved for lifetime.
    - Prior Authorization, Non-formulary, Quantity Limit and Tier Lowering Exception requests will be approved for one year.
        - Based on clinical review, certain drug approval situations may require a shorter approval duration of contract year
        - A next day oversight report is used to monitor for any exception requests that have been approved for less than 1 year.
- Protected class drugs are approved for one year.
    - If a member is adherent to therapy (no gap in utilization greater than 180 days), the drug will continue to auto-adjudicate beyond the one-year approval.
    - Safety Edit requests will be approved throughout the plan year. Based on clinical review, certain drug approval situations may require a shorter approval duration.
    - For requests where a Coverage Determination is not required and the case is covered per the formulary without UM restrictions, Navitus will treat these as approvals and notify the member as required. For reporting purposes, the effectuation date will be equal to the received date, as the member could have filled the medication being requested as of that date without an override.
    - B vs D requests will be approved for one year.
        - For plan sponsors who are not the Part B payer (PDP, EGWP, etc.) a Part B approval would not be issued.
    - The Part D utilization management criteria and formulary status are not applied to Part B eligible drugs.
    - Hospice requests, when determined to be unrelated to the terminal illness and/or related conditions, will be approved for one year or according to the UM criteria, if applicable.
    - If the duration of approval is extended past that was originally communicated, the enrollee must receive written notice at least 60 days prior to the new termination date. The notice must:

- ▪ Explain the exception will not be extended more than 60 days past the notification,
- Provide the date that coverage will end (e.g., on December 31, 2015),
- Explain the right to request a new exception once the current expires and provide instructions for making a new request.

- An approval of a prescription drug claim based on medical necessity, appropriateness, level of care or effectiveness will not be reversed by Navitus unless:
  - A client instructs Navitus to do so OR
  - ▪ Evidence of fraud is discovered in the documentation supporting the original certification.
  - ▪ If a previous approval is reversed, the member and prescriber will receive a standard denial
  - notification indicating the clinical rationale for the denial using the information available at the time of the reversal.
- **Overrides:**
  - When an approval decision is granted for a coverage determination, an override will be entered into the claim processing system to allow the claim to pay at the point of sale. The override is effectuated as of the date of the decision.
  - A test claim will be run to ensure overrides are entered appropriately and claims will process at the point of sale.
  - The pharmacy is notified of an approved coverage determination when there is a rejected claim for the approved medication within 30 days.
  - If the pharmacy requests the approval to be backdated (so they could reimburse the member if they paid out of pocket), the override will be backdated as appropriate.

- **Reopens:**
  - If a coverage determination needs to be reopened and a new review or decision must be made on a case that has not already been reviewed at

the redetermination level, Navitus will reopen the request, and the applicable TAT starts over.

- If additional information or a supporting statement is received at Navitus prior to the original TAT of the request expiring, a case will be reopened to review the information.
- If during an internal audit or oversight, Navitus finds information was not reviewed or included with the original review, the case will be reopened.
- If a decision is made on a B versus D determination where the decision defaults to D, due to lack of information, additional outreach will be performed to determine correct billing. If alternative information is received, the case will be reopened.
- If a case is incorrectly closed as a Duplicate, Dismissal, or Received in Error, the case will be reopened for proper review.
- Once the new review has occurred, new notification letters are issued to the enrollee and prescriber.

Missed Turnaround-Time Requirements:

- Navitus will notify C2C Innovation Solutions, Inc via fax or C2C online portal. The request must be submitted to IRE within 24 hours following the expiration of the adjudication Timeframe.
    - C2C Innovative Solutions, Inc.
    - Fax: (904) 539-4099
    - Portal: https://www.c2cinc.com//Appellant -Signup
- If Navitus makes a completely favorable decision within 24 hours af ter the adjudication Timeframe expires:
    - This is used sparingly and only when approval can be clearly granted based on the information available for the case.
    - The case file will not be forwarded to the IRE.
    - The enrollee will be notified of the approval decision.
    - The standard approval notice will be sent.
    - Email notification containing case details is provided to Government Programs who completes the issue notification.

- If Navitus cannot make an approval decision within 24 hours or it has been greater than 24 hours after the adjudication Timeframe expires, the case is to be forwarded to IRE. Navitus will not decide or send a determination letter to the enrollee.
- Navitus must inform the enrollee within 24 hours following the expiration of the adjudication Timeframe that the case has been forwarded to IRE using the Case Status Model Notice. The notice must advise the enrollee of his/ her right to submit additional evidence that may be pertinent to the enrollee's case, if the enrollee chooses; and direct the enrollee to submit such evidence to the IRE; and include information on how to contact the IRE.
- If the IRE approves the request, Navitus will implement the approval by entering an override and updating the Prior Authorization Record within 24 hours of receipt of the notice from the IRE or Plan Sponsor.
- Navitus will inform the notifying party when the override has been entered.

Definitions:

Adverse Determination	Any unfavorable decision regarding coverage or payment, in whole or in part, for prescription drug Benefits an enrollee believes they are entitled to.

Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance	A coverage determination is any determination (i.e., an approval or denial) made by the Part D plan sponsor, or its delegated entity, with respect to the following: 1. A decision about whether to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out -of network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excluded under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan; 2. Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee; 3. A decision concerning a tiering exceptions request under 42 CFR 423.578(a); 4. A decision concerning a formulary exceptions request under 42 CFR 423.578(b); 5. A decision on the amount of cost sharing for a drug; or 6. A decision whether an enrollee has, or has not, satisfied a prior authorization or other utilization management requirement. See §30.1.
CMS (Centers for Medicare & Medicaid Services	The Centers for Medicare & Medicaid Services, CMS, is part of the Department of Health and Human Services (HHS). The programs CMS administer include: Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Marketplace.

Expedited Coverage Determination	Any decision made by or on behalf of a Part D plan sponsor regarding payment or Benefits in response to urgent/expedited coverage request (oral or written) by the prescribing physician or enrollee. An expedited determination can be requested when the enrollee or prescriber believes that waiting for a decision under the standard time frame may place the enrollee's lif e, health, or ability to regain maximum function in serious Jeopardy. Any indication on the request as urgent will be processed as expedited.
Exception	Tiering exception: If a plan utilizes a tiered cost-sharing structure to manage its Part D drug Benefits, it must establish and maintain reasonable and complete exceptions procedures that permit enrollees to obtain a nonpreferred drug at the more favorable cost-sharing terms applicable to drugs in the preferred tier Formulary exception: If a plan utilizes a formulary to manage its Part D drug Benefits, it must have procedures in place that ensure enrollees have access to Part D drugs that are not included on its formulary, have dose restrictions or apply to transition f ills.
IRE (Independent Review Entity)	An independent entity contracted by CMS to review Part D plan sponsor denials of coverage determinations.
PBM (Pharmacy Benefit Manager)	A pharmacy Benefit manager (PBM) is a third-party administrator (TPA) of prescription drug programs for commercial health plans, self -insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, and state government employee plans.
POS (Point of Sale)	The point of sale is the time and place where a retail transaction is completed.
P & T	Pharmacy and Therapeutics
Redetermination	The first level of appeal which involves a Part D plan sponsor re-evaluating an adverse coverage determination, the f indings upon which it was based, and any other evidence submitted or obtained.

Standard Coverage Determination	Any decision made by or on behalf of a Part D plan sponsor regarding payment or Benefits in response to a routine coverage determination request when the request is not designated by the enrollee or his/her prescribing physician as expedited or urgent.
TAT (Turnaround-Time)	The amount of time allowed by CMS for a plan sponsor to complete a coverage determination request af ter it received.

Formulary Transition Policy

Policy:

Navitus will execute a transition process for new members transitioning to a Navitus plan formulary whose current drug therapies may not be included on the member's formulary. This process will also be executed when current member's formularies are experiencing a negative formulary change. Any changes or modification to this policy and procedure will be reviewed and approved by the Formulary Advisory Committee (FAC) and captured in the FAC meeting minutes. All formulary transition policies, communications and notification timelines are subject to approval from the client.

Formulary (Clinical) Transition for New Members:

- As part of Navitus' new client implementation process when historical claims data are available from the previous plan, Navitus Clinical Account Executive staff will review utilization and determine which medications currently utilized are not part of the new formulary.

- In situations where members are stabilized on drugs that are not on the plan's new formulary and which are known to have risks associated with any changes in the prescribed regimen, the Navitus P&T Committee (or the client's P&T Committee, if applicable) will be involved to ensure that the transition decisions appropriately address the situation. Members taking medications in certain therapeutic categories as determined by the Navitus P&T Committee (or the client's P&T Committee, if applicable) may not be required to transition to a formulary medication. This exception does not include medications for which an A-rated generic exists.
    - Example drug classes may include:
    - Antidepressants
    - Anticonvulsants
    - Anti-psychotics
    - HIV / AIDS

- The Client/Plan Sponsor in collaboration with Navitus' Implementation Coordinator and
    - the designated Clinical Account Executive determine which medications will be part of
    - clinical transition and process details including, but not limited to,:
    - Timeline for transition (generally 3-6 months after plan implementation)
    - Notification Process (Recipients, methods of contact such as letters and web
    - postings, look-back period for claim utilization, goal date for notifications, etc.) Transitional coverage (Tier, applicability to deductibles, max out of pockets, etc)

- Whenever possible (based on availability of member eligibility, member claim history,
    - and finalization of the client's new formulary) and within Client discretion, Navitus will
    - notify new members in writing at least sixty (60) days prior to the client's effective date
    - with Navitus.

- The Navitus Clinical Account Executive, when data is available, will generate a Transition Report using the Navitus Clinical Mailings 3D object which, will generate a
    - report including the following data if available:
    - Kit Name
    - Carrier ID
    - First and Last Name and complete address of member
    - Date of Birth
    - Family and/or Individual Member ID
    - Language Code
    - Complete provider information
    - GPI or NDC for the transition medication
    - Drug Name
    - Carrier Name
    - Plan Name
    - Formulary Type
    - Combined Family and Carrier ID including
    - Person Code

- Using the Transition Report, written communications to new members related to Clinical
    - Transition will include:

- The medications currently covered under their plan which will be not covered or

- covered at a higher tier with Navitus,

- The new coverage level under the Navitus plan (non-preferred or not covered)

- A list of common formulary alternatives for each,

- The transitional coverage tier and time period when applicable,

- Indication that Navitus P&T (or the client's P&T Committee, if applicable) makes
  - formulary decisions and the basis by which these decisions are made,

- The Navitus web address (or the client's web address, if applicable) for
  - accessing the applicable formulary,

- Contact information for Navitus Customer Care (or other applicable contact if
  - Navitus does not provide customer service for the client).

- Using the same Transition Report, the Clinical Account Executive will facilitate entry of
  - overrides for those members using a medication with a transition period
  - (the drug will continue to be covered at a lower patient pay amount for a specified period
  - of time.) The goal is to prevent unnecessary rejections at the point of sale for members
  - who meet the transition criteria and for whom historical claim data is available.
  - Customer Care (or applicable client contact if Navitus does not provide customer service for the client) receives a copy of the communication prior to mailing along with "Talking Points" from the Clinical Account Executive for assistance when triaging calls related to the Transition.

- In the event a new member attempts to refill an existing medication that was not transitioned for them due to a lack of historical data, Customer Care will access the transition communication for that client and enter the appropriate override for the member. The member will be educated on the transition period details. When possible, the member will be mailed a copy of the communication.

- In the event the new member presents a new prescription during the clinical transition period, the member will be instructed to receive a prescription for a formulary alternative or will incur the applicable cost for filling the original prescription.

- Navitus Customer Care (or applicable client contact if Navitus does not provide customer service for the client) receives a request for a new member to receive a transitional fill override for a medication not identified as part of the transition process and/or for a new prescription for a medication covered under the transition process for medical reasons, one or more of the following will occur:
    - Member is granted a one-time override as determined by the plan design and documented in the transition "Talking Points" and/or Client Component Guide.
    - Customer Care (or applicable client contact) reviews the request with a Navitus clinician for approval.
    - Customer Care (or applicable client contact) reviews the request with the Clinical Account Executive for approval.

Formulary Transition (Change) for Current Members:

- Negative Formulary Changes include but are not limited to:
    - A drug product or chemical entity being removed from the formulary.
    - A drug being moved to a higher tier.
    - The addition of or more aggressive use of utilization criteria such Prior Authorization, Step Therapy, or Quantity Limits.

    - All Negative Formulary Changes and appropriate alternatives are approved by the Navitus P&T Committee (or the client's P&T Committee, if applicable) prior to implementation with the following exceptions;
        - Branded medications that have A-rated equivalent generics or an equivalent chemical entity available at an equal or lower tier.
        - Products that have been recalled by the FDA Please see Navitus' Member Safety (Drug Recall Communications) P&P for the recall process

    - If it is determined that a member will be affected by a negative formulary change, Navitus notifies the member at least sixty (60) days in advance of the change.

    - Using a claim utilization Transition Report which is generated by the Navitus Clinical Mailings 3D object, written communications to current users will include:
        - The medication(s) affected by the negative change,
        - The reason for the change,
        - A list of common formulary alternatives,
        - The transitional coverage tier and time period when applicable,
        - Indication that Navitus P&T (or the client's P&T Committee, if applicable) makes

- formulary decisions and the basis by which these decisions are made,
- The Navitus web address (or client web address, if applicable) for accessing the applicable formulary,
- Instructions to contact their prescriber to discuss available alternatives,
- Contact information for LMA Customer Service.

○ When applicable, Navitus will implement claims processing system messaging which informs submitting pharmacies of preferred or covered alternatives for these medications.

○ When applicable, Navitus will generate a FAX Blast to affected pharmacies which will identify the change in formulary and the effective date of the change.

○ When applicable, the Clinical Account Executive or designee will facilitate entry of clinical transition overrides for those members using a medication with a transition period (the drug will continue to be covered at a lower patient pay amount for a specified period of time.) The goal is to prevent unnecessary rejections at the point of sale.

○ If a 60 day member notice is desired, then the transition period on the override should be 90 days to ensure time to review and generate letters.

Definitions

Clinical Account Executive (CAE)	Navitus pharmacist assigned to manage clinical aspects of a client's pharmacy benefit.
Formulary Transition (Change)	Change in drug coverage for Navitus members.
Formulary Advisory Committee	Routine P&T sub-committee composed of pharmacists and physicians that addresses day-to-day issues related to drug therapy that require attention more immediately than can be accommodated by the P&T meeting schedule

P & T Committee	Committee composed of clinicians who serve as the clinical oversight body for all clinical criteria employed in Navitus programs to ensure promotion of rational, clinically appropriate, and safe drug therapy.
A-rated generic	A generic determined to be therapeutically equivalent to the brand name drug by the Food and Drug Administration (FDA)
3 D	Navitus's proprietary reporting tool
GPI	Generic Product Indicator
NCD	National Drug Code
NCQA	The National Committee for Quality Assurance is a independent organization that works to improve health care quality through the administration of evidence-based standards, measures, programs, and accreditation.
URAC	An independent organization that helps promote health care quality through the accreditation of organizations involved in medical care services.