NCPDP Specialty Pharmacy Benefit Coverage Identification White Paper

Version 10

September 2020

This document highlights the current challenges experienced by providers, dispensers and organizations in being able to timely and accurately identify the appropriate benefit coverage (medical or pharmacy benefit) for a specific medication being prescribed, as well as potential out-of-pocket costs to the patient, at the time of care.

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The task group members, document authors and other contributors of this paper will review and possibly update their recommendations should any significant changes occur.

This document is for Education and Awareness Use Only.

1 PURPOSE

The purpose of this white paper is to highlight current challenges experienced by providers, specialty pharmacies and organizations in being able to timely and accurately identify the appropriate benefit coverage (medical or pharmacy benefit) for a specific medication being prescribed, as well as potential out-of-pocket costs to the patient at the time of care. Overall, the desired outcome of benefit identification is to provide a comprehensive benefit coverage overview electronically at the time the medication is selected and to improve a patient's ability to begin therapy without delay. This process should be easily accessible without multiple manual steps or duplication of efforts by providers, specialty pharmacies and hubs.

The NCPDP Specialty Pharmacy Workgroup created a task group with the specific purpose of focusing on benefit identification to investigate ways to streamline the process with electronic workflows. The Benefit Coverage Identification Task Group determined a white paper was needed to level set the current state for industry participants. This paper will focus on specialty pharmacy to:

- Identify current state for participants in specialty medication prescribing and dispensing to understand if coverage is through the medical or pharmacy benefit.
- Understand gaps in current standards, opportunities to leverage existing standard capabilities and create coordinated progress across potential standards-based solutions.
- Identify opportunities across various stakeholders for collaboration to improve the process.
- Address the areas of opportunity related to determining whether coverage is through the medical or pharmacy benefit.

It is recognized there may be other pharmacy types (retail, outpatient hospital, etc.) that may have common challenges related to the topics covered in this white paper. The scope for this white paper is focused on specialty pharmacy. This does not rule out the opportunity to develop and publish additional guidance to address the unique issues and processes of other pharmacy types.

2 BACKGROUND

Specialty medications are generally defined as those of high cost or requiring special handling. From a benefit perspective, these medications are unique, because they can be covered under the medical or pharmacy benefit or both. Providers are attempting to determine the benefit with maximum coverage for their patients. The combinations for coverage are varied, and there are no standards in the industry to determine if a specialty medication is covered by a medical or pharmacy benefit. Additional factors such as patient, specialty medication, bundled specialty medication and service, plan, pharmacy and place of administration add to benefit coverage confusion. The result is different processes for different specialty medications or plans. Providers typically start the prescription process with a search for information through a phone call or payer portal. Certain healthcare settings may try to utilize medical or pharmacy benefits as a default. Due to the complexity of specialty medication coverage, they are often forced to take multiple manual steps outside electronic prescribing workflows. These factors can lead to suboptimal benefit utilization, higher out-of-pocket costs and delays in therapy.

Specialty medications pose problems not seen with typical prescription medications. There can be different determination of benefits based on the site of administration (e.g., home or clinic) as well as limitations on where the specialty medication can be dispensed. On the medical side, services are typically rendered, and insurance is verified but not billed until a later time. For medications covered under pharmacy benefits, billing is in real-time utilizing the NCPDP Telecommunication Standard which allows claims to be adjudicated prior to dispensing and identifies any payment issues at the point of dispensing. With specialty medications these multiple billing processes can lead to unexpected financial ramifications for the patient, provider and payer. Having a clear path for pharmacy versus medical benefit identification is desperately needed today.

Duplicate workflows are common today in the benefit identification process. The goal is to determine the most appropriate benefit by checking both medical and pharmacy benefit coverage. Manually verifying coverage can be a significant resource drain and is very inefficient and often causes undue delays in processing and filling prescriptions. Phone calls are often the best mechanism for completing this type of duplicate benefit investigation. Often calls can take over 30 minutes including multiple transfers, inconsistent information and extended delays due to high call volume.

Below is an example of how complex and different the process can be for a commonly used specialty medication.

Example:
Specialty medication: Humira®

1. Insurer #1 Humira® is on formulary
    a. Pharmacy benefit: Can only be filled at certain specialty pharmacies
    b. Medical benefit: Can only be billed as a bundled service by a Rheumatoid Arthritis (RA) specialist
2. Insurer #2 Humira® is non formulary, Enbrel® is preferred
    a. Pharmacy benefit: Will require prior authorization to fill Humira® or Enbrel®. Humira® may result in a higher out-of-pocket cost
    b. Medical benefit: Not covered

3 BENEFIT INVESTIGATION FOR SPECIALTY MEDICATIONS - CURRENT CHALLENGES

Diverse work practices, multiple discovery methods, duplicative investigation efforts, multiple standards, limited electronic transactions and non-viable data flows contribute to the current challenges in benefit investigations.

3.1 INCONSISTENCY IN COVERAGE AND PRACTICE

Specialty medications can be covered as medical, pharmacy or under both benefits. Payers vary with respect to their requirements. Based on the payer, the determination may be set by the way the specialty medication is requested, as a medical order versus a prescription. In addition, the care setting, or health system organization, may have their own preference on how to submit the request - order versus prescription. A provider's lack of understanding of which of the patient's payers own the benefit may delay fulfillment of the order due to confusion of benefit coverage for the patient. This also may result in the patient paying more for the benefit or the provider not getting the best reimbursement rate.

3.2 REALITY OF BENEFIT IDENTIFICATION INQUIRY ACROSS STAKEHOLDERS

Duplication of effort occurs not just at the preliminary determination of whether the specialty medication is covered under the medical or pharmacy benefit, but also occurs at the separate entities involved in the dispensing of specialty medications including hubs and specialty pharmacies. Such examples include:

1) The specialty pharmacy could be doing benefits investigation at the same time as the hub
2) The hub may not know the specialty pharmacy is also verifying and/or dispensing
3) Some payers will send information to the specialty pharmacy although the hub is assisting with prior authorization (PA)
4) The provider's office may aid and/or participate with one or more parties listed above further duplicating efforts

Duplicative efforts happen due to the opaque nature of the current process and with the provider's desire to increase speed to treatment. From a provider perspective, there may not be a direct cost to simultaneously send inquiries and information to multiple entities to see which can provide the information faster. Due to the lack of clarity as to what coverage applies to what specialty medication, providers may well find it easier to send out multiple requests than be discrete in their outreach. The result of this approach can be duplication of efforts resulting in:

1) Sending multiple queries to determine coverage
2) Gathering information from multiple sources
3) Accepting the first response as the most appropriate benefit
4) Receiving inconsistent information from multiple sources

Discovery of pharmacy and/or medical benefits, via the phone or a web portal, is presently required to understand which option is best for the patient. Benefits may be retrieved via a call to the number on the patient's insurance card, via a portal, or even by placing a call to a number referenced on the portal. Standard transactions may also be used to determine benefit information.

The following are other factors that contribute to duplication of efforts in verifying a patient's benefit coverage:

1) Differences in coverage by payer
2) Differences in coverage by specialty medication
3) Duplicative or unclear established Healthcare Common Procedure Coding System (HCPCS) J code for existing products
4) New to market products with no established Healthcare Common Procedure Coding System (HCPCS) J code
5) Patient adherence concerns
6) Hub services
7) Patient assistance program availability
8) Pharmacy network status

Given the multiple pathways, complexity and variability for benefit investigation today, duplication is inherent to the current system and drives inefficiencies impacting prescribers and patients alike. The focus should be on increasing automation. Clarifying best practices for who is responsible to identify benefit coverage and initiation of the request is needed. Therefore, it is imperative we establish a common standardized method to complete this work to reduce providers' burdens, improve patient safety and access to their needed specialty medications.

3.3 STANDARDS AND TRANSACTION LIMITATIONS

The currently available electronic transactions can support certain steps in the benefit investigation process but do have limitations. These standard transactions are limited to the scenarios where they are used. An example of current limitations: Prior to an appointment the treatment plan may not be known, so coverage inquiries are limited in the value of the information that can be provided. The requests are often automated, sent by the system for all patients who have a scheduled appointment for a future date. This type of inquiry is simply looking to determine if there is coverage for the visit.

3.3.1 Eligibility

The most common way to access patient eligibility for a specialty medication and coverage information including details on formulary information is via the X12 Health Care Eligibility Benefit Inquiry and Response (270/271) transactions. Since specialty medications can be covered under pharmacy or medical benefit, an eligibility transaction may be sent to both payer types.

Medical Benefit:

Eligibility requests are mandated by Health Insurance Portability and Accountability Act (HIPAA) to use the X12 Health Care Eligibility Benefit Inquiry and Response (270/271) transactions.[1]

Pharmacy Benefit:

[1] https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Transactions/HealthPlanEligibilityBenefitInquiryandResponse.html

Eligibility requests used in e-Prescribing are mandated by the Medicare Modernization Act (MMA) to use X12 Health Care Eligibility Benefit Inquiry and Response (270/271) transactions.[2]

Transactions typically are sent at various stages such as pre-appointment and post appointment (See opening paragraph of Section 3.3). Often the payer being queried does not know how much data needs to be returned in order to allow sufficient benefit insight to the provider sending the request. Providers need a way to inform the payer of the nature of the eligibility request. Current transactions do not allow for providers to submit the stage of care a patient is in to allow for maximum specificity of data to be returned. A challenge with pre-service scenarios is that the eligibility request medication information is not sent. Again, this is most often due to the nature of when the request is being made (before the visit and/or treatment decision). The X12 270 Health Care Eligibility Inquiry does allow for the ability to inquire about a specialty medication utilizing the National Drug Code (NDC). In the X12 271 Health Care Eligibility Response, payers may support returning the NDC but not all are utilizing this feature today. The current guidance for the X12 5010 version of the Health Care Eligibility Inquiry and Response allows payers to support the use of NDC at their discretion. This may be an area of opportunity for future standard enhancements.

The following depicts a potential transaction sequence today*, please note common ***limitations as well:*

i) The patient has a scheduled visit with the provider which is captured in the Electronic Health Record (EHR)
ii) 24-72 hours prior to the visit, EHR submits a X12 270 Health Care Eligibility Inquiry to either or both the pharmacy and medical benefit plan(s)
iii) The plan replies with a X12 271 Health Care Eligibility Response

****This request for eligibility is often limited by trading partner agreement to once in a 72-hour timeframe for the pharmacy benefit.*

****Service type code is pre-service; therefore, the payer returns minimum benefit information, e.g., eligible member, office visit covered.*

(1) The provider meets with the patient, resulting in a specialty medication need; therefore, additional coverage information being needed

iv) Prescription for specialty medication is sent to a specialty pharmacy/hub
    (1) To determine pharmacy benefit eligibility and coverage, a NCPDP Telecommunication Standard claim billing request transaction is submitted to the Pharmacy Benefit Manager (PBM)
        (a) If covered, the pharmacy dispenses the specialty medication
        (b) If not covered, the pharmacy must delay therapy and contact the provider (e.g., to change the specialty medication, initiate the PA process) or charge the patient cash for immediate dispensing

[2] https://www.cms.gov/Medicare/E-health/Eprescribing/index.html

**** Specialty medication may or may not be covered by pharmacy benefit and not discovered until the prescription is at the pharmacy.*

(2) To determine medical benefit eligibility, a X12 270 Health Care Eligibility Inquiry is sent to the medical benefit plan
   (a) The plan replies with a X12 271 Health Care Eligibility Response
   (b) After the visit, the EHR submits a X12 837 Healthcare Claim transaction to the payer requesting payment for medical services supplied by the provider
   (c) Payment information is sent via the X12 835 Healthcare Claim Payment/Advice transaction from the payer to the provider(s) for medical services

****If the specialty medication is not covered by medical benefit, reimbursement may not occur and then the patient may receive a large bill. This could also lead to therapy changes in future dispensings.*

3.3.2 NCPDP Formulary and Benefit Standard Files

The eligibility transactions described above also serve another purpose in the benefit identification process by providing formulary and pharmacy benefit pointers. EHRs use the pointers to query formulary and benefit files provided by the payers periodically. These formulary and benefit files allow for identification of plan level, not patient level, pharmacy benefit coverage information that can be utilized during the patient office visit.

Formulary & Benefit Standard process:

Periodic data retrieval:

1. The Formulary Publisher (PBM)/Payer) develops and sends a formulary file to an intermediary
2. After validating the files, the intermediary creates a response file for the PBM/Payer, loads the files into a database and creates a host file for real-time formulary subscribers
3. The Formulary Retriever (Requestor), which is typically a provider's EHR, downloads and stores the formulary files for use at a later time or is enabled for real-time formulary transactions with an intermediary that hosts the formulary files. While the formulary transactions may be conducted in real-time, the data contained within those files is updated at variable intervals, therefore not real-time.

Patient visit or prescribing event:

1. A requester sends a Health Care Eligibility Inquiry (X12 270) to an intermediary.
2. The intermediary validates the format of the incoming Health Care Eligibility Inquiry and locates the patient based on demographic information
3. The intermediary determines to which PBM/Payer(s) the Health Care Eligibility Inquiry (X12 270) is sent
4. The PBM/Payer(s) verifies the patient and responds to the intermediary with a Health Care Eligibility Response (X12 271) indicating the patient's eligibility status
5. The intermediary validates the format of the incoming Health Care Eligibility Response (X12 271), consolidates all X12 271 Health Care Eligibility Responses and sends the information back to the requester

6. The requestor uses key data from the X12 271 Health Care Eligibility Response to determine appropriate formulary files which have been downloaded as noted in the formulary process above for the specific patient being requested in the eligibility request/response. Important information that is returned includes:
    1. Health Plan Number/Name
    2. Cardholder ID
    3. Relationship Code
    4. Person Code
    5. Group Number/Name
    6. Formulary ID
    7. Alternative List ID
    8. Coverage List ID
    9. Copay List ID
    10. BIN/IIN
    11. Processor Control Number (PCN)

With the appropriate formulary, alternative, coverage and copay IDs, the EHR can display data to the provider about the group coverage the patient has.

Formulary and benefit information adds another layer of coverage information a provider can use. However, lack of medical benefit information in the process prevents accurate determination of the most appropriate benefit. Enhancements to these processes by new versions of the NCPDP Formulary and Benefit Standard will provide more clarity to providers. Movement to a newer version of the Standard is controlled under the MMA. It is important that payers take advantage of the ability to share this data with providers so more prospective benefit decisions can be made at the point of care.

3.3.3 Health Care Services Review

The X12 278 Health Care Services Review Information transaction is another means to assist with benefit identification, typically on the medical benefit. The X12 278 Health Care Services Review Information transaction is a paired transaction set consisting of a Request and a Response. It is used to electronically submit authorization and referral requests. An authorization is a review of services related to an episode of care and a referral is used to refer a member to a specialty provider.

1. This transaction set is generally used as a 'next step' following an appointment for the medical benefit. The provider will submit a X12 278 Health Care Services Review Information request (via an EHR) to the member's medical insurance company to inquire or notify them of the following:
    - Current coverage
    - Scheduled inpatient or specialty care
    - Patient arrival or discharge from a facility
    - Health services information sent to service providers
    - Changes to previously sent information
    - Desired diagnostic and treatment plan

2. Quality of data returned in the X12 278 Health Care Services Review Information response varies by vendor and payer capabilities and can impact usability for the requester. The variability may or may not include:
    - Details on specific products and services covered
    - PBM benefit owner
    - Authorization requirements

Challenges with the X12 278 Health Care Services Review Information transaction include a low level of automation and lack of granular details of coverage. There is a need for patient-specific benefit information to be given to the provider within their workflow.

Increasing complexity of medical and pharmacy plan designs, including high deductible health plans and shared risk payer contracts, are making complete benefit identification a vital need for providers. Across the industry, workflows will need to be adjusted to allow for more detailed pre-service information. Also, more specific requests may need to be sent when a treatment plan is determined. When the appropriate specialty medication has been identified, updated benefit coverage information may be required.

4 UNDERSTANDING THE CURRENT METHODOLOGY

4.1 CURRENT STATE PROCESS WORKFLOWS DESCRIPTION

Understanding the current methods and tools is valuable in identifying areas that could be leveraged to improve the processes. For example, the eligibility transaction set that is widely used (X12 270/271 Health Care Eligibility Inquiry and Response) has the ability to support more granular requests and responses, but the industry has not yet adopted those features. The transaction for prior authorization (X12 278 Health Care Services Review Information) was not designed to support medication specific requests and therefore is not widely used for that purpose. The NCPDP SCRIPT Standard electronic prior authorization transactions were designed to support medication-specific requests in real-time but specifically for the pharmacy benefit. The table below describes the relevant standards that support benefit investigation today.

Standards Organization	Standard name	Standard used for
NCPDP	SCRIPT Standard	Electronic Prior Authorization
NCPDP	Telecommunication Standard	Benefits and Eligibility Investigation (E1 Eligibility Transaction)
NCPDP	Real-Time Prescription Benefit Standard	Pharmacy Benefits Inquiry and Response
X12	278 Transaction	Health Care Services Review Information
X12	270/271 Transaction	Health Care Eligibility Benefit Inquiry and Response
HL7	Fast Healthcare Interoperability Resources (FHIR®)	Application Programming Interface (API) for exchanging health records information

Most of these standards enabling benefit identification lack adequate adoption or maximal usage of available data fields to solve the benefit investigation puzzle. The following are examples of disparate use of standards in the industry:

- X12 270/271 Health Care Eligibility Inquiry and Response – though the transactions are widely adopted, many supported features/elements are not widely adopted such as provider type, diagnosis code(s), PA indicator, pharmacy provider type.
- X12 278 Health Care Services Review Information transaction has low adoption, especially for medications. PBMs are generally responsible for handling medication PA requests when covered under the pharmacy benefit; whereas, the health plan is responsible for processing X12 278 Health Care Services Review Information requests for specialty medications covered under the medical benefit.
- HL7 FHIR® is an emerging standard. It has yet to be fully defined as to how it can support benefit investigation.
- The NCPDP SCRIPT electronic PA (ePA) transactions are widely adopted and utilized in the industry today for specialty medications covered under the pharmacy benefit.

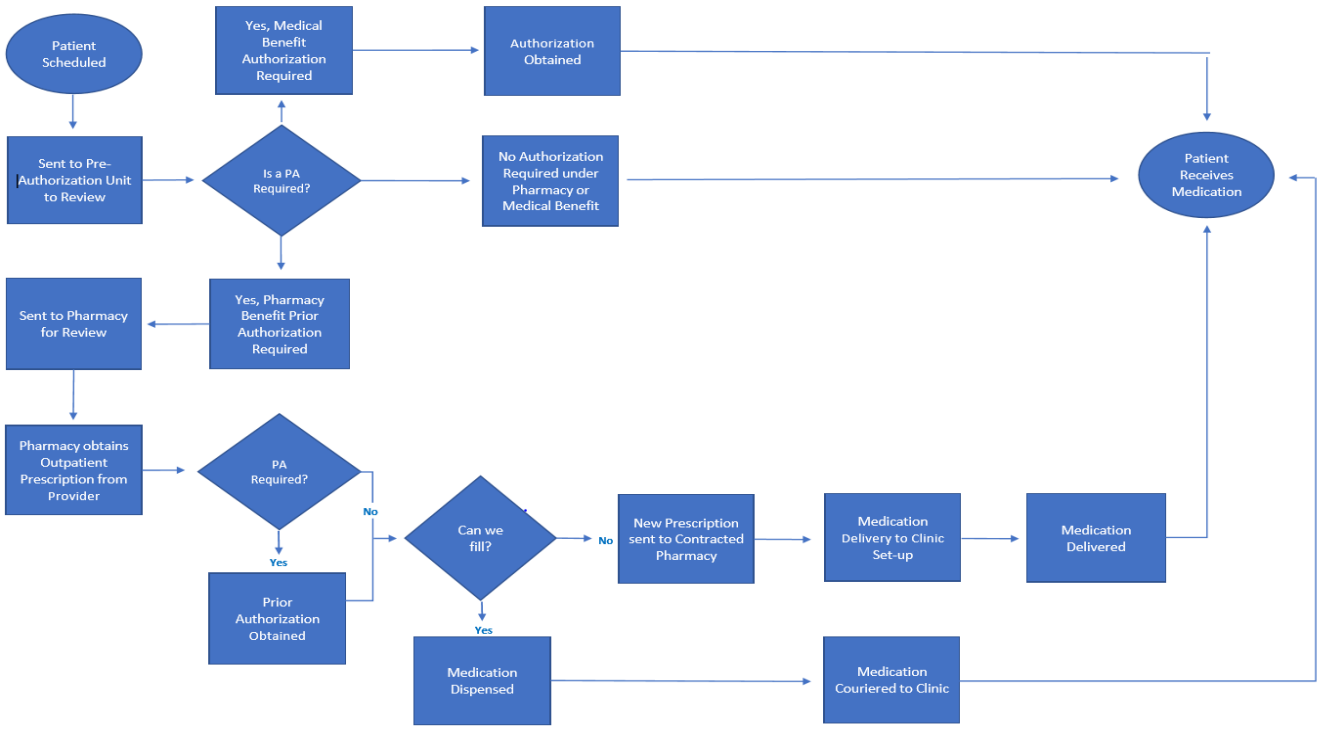
Other barriers to expedite the benefit investigation process are:

- PBMs are able to return data electronically in real-time; however, the transaction(s) may lack necessary data to accurately identify the patient's coverage options.
- Conversely, the health plan may have all the patient information needed for full benefit investigation but lack a means to electronically communicate the data to providers.
- Payers may receive an X12 278 Health Care Services Review Information request but have delegated utilization management to another entity. The payer's response to the X12 278 Health Care Services Review Information request may indicate only that PA is required. Payers may forward the request to their utilization management entity or direct the requester to resubmit to the appropriate entity.
- Many payers have opted to use portals to handle PA requests. These portals all vary, although most follow, to some extent, the X12 278 Health Care Services Review Information content. Use of portals requires providers to maintain login credentials to each and limits interoperability.
- Payers have also created proprietary transactions to obtain data required to process PA and other data needed for claim processing. These solutions are not standardized and are therefore difficult to adopt across the industry.

An example would be the utilization of drug and diagnosis codes in electronic transactions. If those fields were consistently populated by providers in their EHR system, then payers could return more relevant data. In addition, some payer systems are not setup to respond to this data due to a low likelihood of receiving the information today.

Providing all the data a payer has for every patient can be problematic as well. Providers could be overwhelmed by the volume of data on a patient as well as relevancy of the content to the current situation. This manner of information sharing does not provide value – leading to increased delays and potential frustration – ultimately leaving the provider (and the patient) in a situation where they still do not know what benefit would be most appropriate.

4.2 HEALTH SYSTEMS EXAMPLE PROCESS FLOW DIAGRAM AND STEPS



Health System Process Workflow Steps

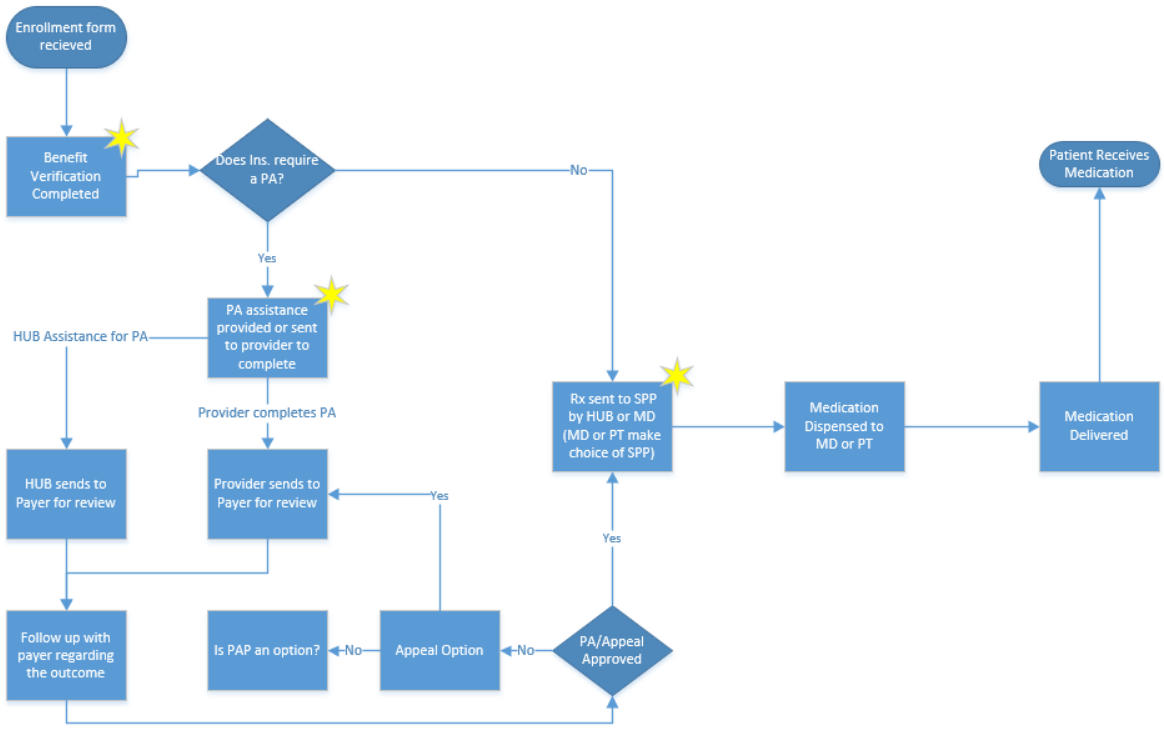
The process flow diagram was taken from an actual health system, the intent was to show gaps in the current process.

1. Schedule patient (typically done prior to appointment by EHR scheduling system)
2. The order is sent to Pre-Authorization Unit for review once specialty medication need is determined
3. Patient goes through Pre-Authorization review. Does insurance require a PA?
    a. No – Proceed to dispense and deliver specialty medication to patient
    b. Yes - PA required
        i. Medical Benefit PA
            1. File a PA Exception – i.e. patient is locked into a specific specialty pharmacy or mail order and there is justification for continuity of care
            2. Medical Necessity – May occur when patient is new to therapy
            3. Non-Formulary – Alternatives that may be covered under Medical Benefit
            4. Quantity Limit Exceeded
            5. Site of Service -Payers not covering infusions at a facility
        ii. Pharmacy Benefit PA
            1. Message sent to provider requesting a prescription be sent to specialty pharmacy for review
                a. Once script is received – does it need a PA?
                    i. If yes, work to obtain PA
                        1. PA Approved – proceed to fill order

ii. If no PA is obtainable, can we fill?

4. Can we fill?
    a. Yes, pre-determine patient's responsible amount and potentially seek co-pay assistance if needed (i.e. for instances of large cost share, deductibles, etc.)
        i. Dispense specialty medication – if infusion goes to infusion center
        ii. Specialty medication delivered to infusion center – distributed to patient
        iii. If both insurances (Medical, Pharmacy) apply, go through medical benefit first to assist with co-pays and meeting deductibles
    b. No, we cannot fill - Some health systems may require all prescriptions be dispensed from a preferred pharmacy, no opportunity for PA or PA Exception
        i. Notify provider that a new prescription needs to be sent to the preferred contracted specialty pharmacy
        ii. Authorized pharmacy responsible for delivery of specialty medication to patient
5. Order sent to Specialty pharmacy
6. If a Specialty Pharmacy can fill a specialty medication through a pharmacy benefit, determine patient's responsible amount and potentially seek co-pay assistance (for instances of large cost share, deductibles, etc.)
7. Dispense specialty medication – if infusion goes to infusion center
8. Specialty medication delivered to infusion center – distributed to patient
9. If both insurances (Medical, Pharmacy) apply, go through medical benefit first to assist with co-pays and meeting deductibles

4.3 HUB EXAMPLE PROCESS FLOW DIAGRAM AND STEPS



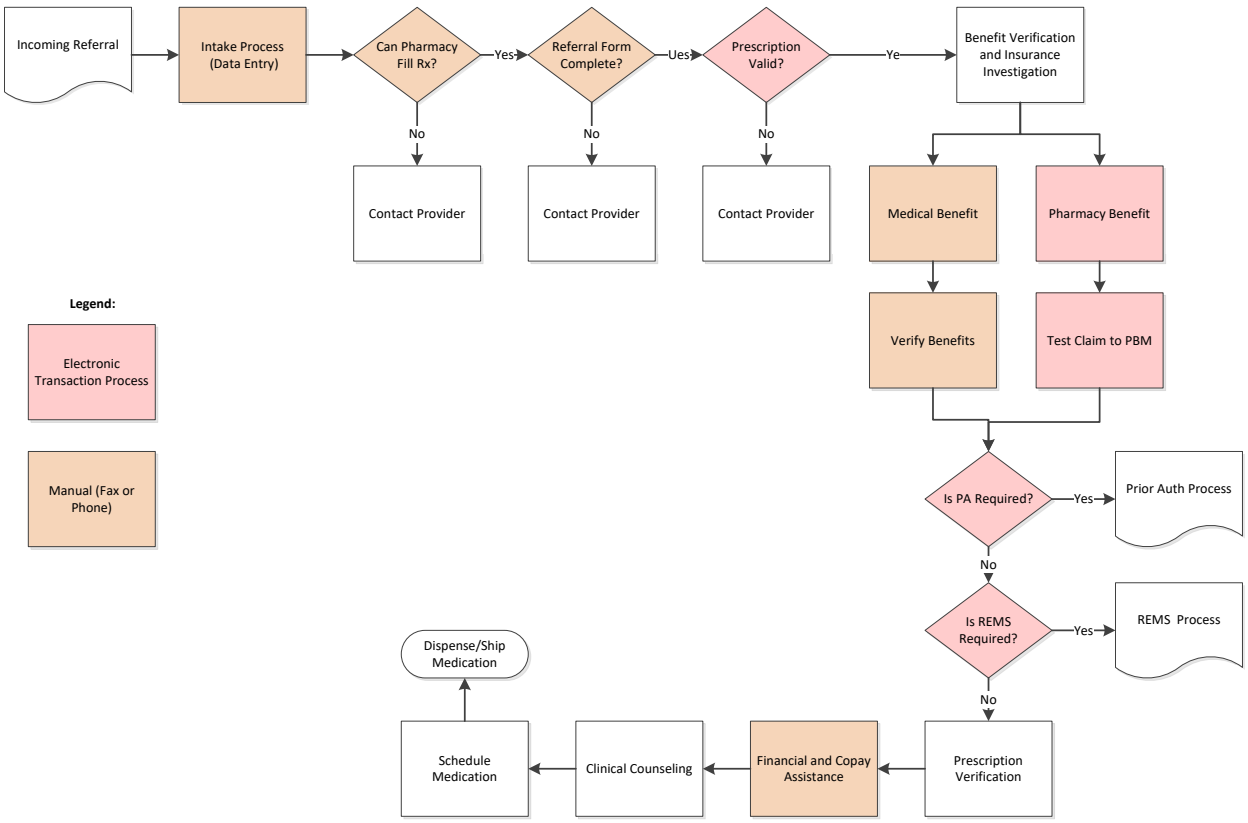
The Yellow Star indicates where electronic transaction is taking place within the current process:
1. Benefit Verification can be done via, E-BV, BV prediction and/or manual BV.
2. Prior Authorization can be done via E-PA and/or manual PA.
3. Rx prescription can be sent to the SPP via file transition or manual fax.

Hub Process Workflow Steps

1. Yellow Star on diagram represents where technology is developing or may occur
   a) Technology referenced in the diagram includes both proprietary and standard solutions.
2. The hub receives the enrollment form via fax or from portal
3. For benefit verification, the X12 270/271 Health Care Eligibility Benefit Inquiry and Response does not go to the benefit level
   a) Manual benefit level verification is still needed
4. Benefit prediction: what will the benefits look like for the patient given their group?
5. Is prior authorization is required?
6. If Prior authorization is required, identify if the PA method is ePA or manual. Hub process is the same regardless of the method of the PA process. Efficiencies are built into the electronic process to decrease turn-around time
7. The hub can assist with the PA form and getting it to the provider for signature. This could be the hub simply providing a blank PA form to the provider
8. Hub can provide assistance by following up with payer
9. It was noted that the hub is likely to be simultaneously researching both pharmacy and medical benefits to get the patient on the appropriate therapy as quickly as possible. However, many times the hub may choose the first benefit that covers the medication rather than the most beneficial to the patient
10. Hub will use knowledge of previous benefit coverage to determine most appropriate benefit

11. Hub can assist in determining which pharmacies are eligible to dispense
12. It is patient choice as to which pharmacy although coverage levels may vary
13. Once the PA is obtained, the hub or provider sends the Rx to the pharmacy

4.4 SPECIALTY PHARMACY PROCESS FLOW



Specialty Pharmacy Process Workflow Steps

This diagram represents the different steps required when filling a specialty medication. The steps may vary in the order the pharmacy performs the steps, but most are required in the dispensing process.

1. The first part of the process is receiving the prescription and verifying if the pharmacy is able to dispense the specialty medication, has the required information for dispensing in the referral form and the prescription is complete and valid
2. The pharmacy would then perform a benefit verification process to understand if the specialty medication is covered under the patient's medical or pharmacy benefit and if a prior authorization needs to be submitted
3. One part of the process for certain specialty medications would require the pharmacy to complete a Risk Evaluation and Mitigation Strategies (REMS) program that is specific to that specialty medication

4. Once the pharmacy is able to verify coverage and complete REMS requirements, if applicable, the next steps would be to verify the prescription along with providing any financial and copay assistance to help the member with payment
5. The final steps of the process are providing any clinical counseling the patient may need regarding the therapy to ensure proper administration and adherence. Once this step is complete, the pharmacy will coordinate delivery and ship the specialty medication

The process flow diagrams above are not all inclusive, and there may be additional steps required in order to advance to any stage noted in the diagrams. This may include validating secondary insurance benefits, refill re-verification process, identifying co-pay assistance options/sources, etc.

4.5 BENEFIT IDENTIFICATION COMMON QUESTIONS

Common questions arise during benefit identification today. The table below shows the most noted questions from each of the stakeholders in the process as discussed during NCPDP Stakeholder Action Group meetings. Lack of clear communication of health information between parties results in duplication as has already been discussed. Below is a summarization of data from each stakeholder at various steps in the process.

Pre-visit eligibility check	Was eligibility returned? Pharmacy benefit or medical benefit?	Was eligibility response complete?	Does EHR have medical data?	Was medical data checked for office visit coverage?
Specialty Prescription written	Did Formulary & Benefit process work?	Did provider send paper, fax or electronic prescription?	Where will specialty medication be administered?	Is the diagnosis and/or indication included on the prescription?
Real-time pharmacy benefit check	Did pharmacy benefit cover specialty medication?	Did pharmacy benefit imply medical benefit coverage?	Was this best price option?	Are other coverage restrictions present or is prior authorization required?
Medical coverage check	Was there historical fill data that determined medical benefit had been used?	Was a medical benefit portal used to identify medical benefit coverage?	Does existing medical order require prescription?	
Prescription filled by specialty pharmacy or hub	Can specialty pharmacy or hub fill?	Is there an enrollment process?	What is most appropriate benefit for patient?	Are all available payers being used? (i.e. primary and secondary)
Dispensing	Did script go to correct pharmacy?	Is pharmacy in optimal network?	Was the specialty medication dispensed before coverage confirmed?	Was medical coverage used?

5 BENEFIT INVESTIGATION CONSIDERATIONS REGARDING EXISTING FUNCTIONALITY

As described in Section 4, benefit investigation functionality is far from completely electronic or even a standard process flow. Coverage for a specialty medication is dependent not only on the specialty medication itself, but also on the location of the specialty medication administration (e.g., provider's office, inpatient, at home) as well as the benefit package of the patient's insurance plan. In order to obtain accurate medical coverage information, providers must have, at minimum, patient demographics, diagnosis, specialty medication, treatment plan and specialty medication treatment location. Each medical carrier has their own coverage model and their own process. The provider's journey to obtain benefit information may start with a standard X12 270/271 Health Care Eligibility Benefit Inquiry and Response inquiry. With the increased adoption of HL7/FHIR®, providers may receive benefit information within the electronic medical record. However, the provider may need to use a mix of phone calls, interfaces with payer portals and faxes.

Multiple functionalities exist today to perform benefit investigation. There is a lack of consistency on the functionality that is used across the industry. Simplifying the processes will require moving to more standardized electronic processes. Before that can happen a thorough understanding of the existing processes is required.

Method	Description
Telephone calls	Primary method for benefit investigation on medical side, also used in some cases for pharmacy benefit outlier questions.
Portal	Used for medical benefit investigation with at least one portal per insurer. Pharmacy benefit portals also exist but typically involve later stages of benefit usage, such as prior authorization.
Fax	Used in some cases for medical benefit inquiry if phone or portal methods are not available. Used less often in pharmacy benefit investigation.
Health Care Eligibility Benefit Inquiry and Response (X12 270/271)	Primary method for pharmacy benefit investigation. Also, used in medical benefit but transactions often lack specificity needed to prevent a phone call.
Health Care Services Review Information (X12 278)	The request for review allows a healthcare provider to request authorization from a health plan or utilization management organization for a referral to a specialist, hospital admission or healthcare service or supply.
Additional Information to Support a Health Care Services Review (X12 275)	A standard electronic attachment transaction used when the need arises for additional information to be submitted to a payer for review to support an electronic claim.

Method	Description
NCPDP Telecommunication Standard Eligibility (E1) Transaction	An eligibility transaction intended to provide the status of a beneficiary's health plan covering the individual, along with details regarding primary and supplemental coverage if applicable.
HL7/FHIR® Coverage Requirements Discovery	With a FHIR® based API, providers can discover in real-time specific payer requirements that may affect the ability to have certain services (including medications) or devices covered by the responsible payer.
HL7/FHIR® Document Templates and Coverage Rules	The Document Templates and Coverage rules specifies how payer rules can be executed in a provider context to ensure documentation requirements are met.
HL7/FHIR® Prior Authorization Support	The Prior Authorization Support defines a mechanism for submitting prior authorization requests in a manner that is mappable to the corresponding X12 transactions, 275 Additional Information to Support a Health Care Services Review and 278 Health Care Services Review Information.
NCPDP Formulary and Benefit Standard	*Formulary and Benefit Standard* provides a standard means for pharmacy benefit payers (including health plans and Pharmacy Benefit Managers) to communicate formulary and benefit information to providers via technology vendor systems. The information exchanged includes formulary status, preferred alternatives, benefit coverage and copay information. This information is provided at the group or plan level.
NCPDP Real-Time Prescription Benefit (RTPB) Standard	*Real-Time Prescription Benefit (RTPB) Standard* was designed to conform to providers' existing workflows and support interoperability with real-time, standardized transactions for the secure exchange of clinical and administrative healthcare information. The *RTPB Standard* enables the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identifies coverage restrictions and alternatives when they exist.

6 EXPECTED RESPONSIBILITIES AND ROLES ACROSS THE SPECIALTY PROCESS

This section identifies the responsibilities for each actor in the specialty process specifically in the current state.

6.1 ACTORS

- Electronic Health Record vendors
  Most EHR providers and pharmacy systems provide the capability to perform an Eligibility transaction to validate coverage. Some EHRs provide secondary/tertiary coverage with commercial or Medicaid payers. Most systems do not provide medical benefit verification in computer prescription order entry (CPOE). It would benefit the BI (Benefit Investigation) process to have all coverage types for a specific patient. Most EHR systems are designed to capture patient information and support clinical documentation and billing.

- Medical Benefit Provider
  Medical Benefit Providers offer coverage that may be the entirety of insurance coverage for a patient or a medical only benefit. They determine what products and services are covered, often through a network of preferred providers, and at what cost to the patient. Medical benefit providers frequently offer portals that allow benefit investigation to be done by care providers.

- Pharmacy Benefit Provider
  PBMs provide coverage of medications for a patient through a predetermined formulary and network of participating pharmacies based on the rules of the plan sponsor. They may offer other services, such as clinical utilization management programs (e.g., prior authorization). PBMs may provide coverage for specialty medications in only certain practice settings and defer to the medical benefit provider in others.

- Pharmacy/Specialty Pharmacy
  Pharmacies are responsible for dispensing the prescribed medication in accordance with applicable laws and regulations. A specialty pharmacy may dispense only specialty medications and be designated as the preferred pharmacy by a medical or pharmacy benefit provider. The pharmacy will research:
  1. If the specialty medication is covered under a pharmacy or medical benefit and if a patient is potentially 'locked out' to a specific specialty pharmacy or PBM Specialty Pharmacy
  2. Patient out-of-pocket financial responsibility amount
  3. If there is secondary insurance to assist patient with co-pay or deductible
  4. Access to patient assistance (grants, copay assistance, etc.) or even providing resources for the patient to receive medication directly from specialty medication manufacturers if the patient lacks the ability to pay for the medication

- Providers
  Providers could include prescribers, pharmacists or their delegates. Care providers are on the front lines with the patients trying to confirm a diagnosis and initiate a treatment plan. Benefit identification comes secondary to these functions. However, as more specialty medications come on the market, cost considerations are moving up the priority list with the advent of shared risk

models such as Accountable Care Organizations (ACOs). Providers, or their delegates, are often forced to work with the EHR and multiple portals to try and determine coverage information. In some cases, they will enter into contracts with pharmacists or other care providers who will assist in benefit identification processes. Changes are needed to move clear identification of maximally effective benefits further up in the provider's workflow to aid in clinical decision support.

- Risk Evaluation and Mitigation Strategies (REMS) Programs Administrators

  Another wrinkle in benefit identification is Risk Evaluation and Mitigation Strategies (REMS) programs. While not a true component of the benefit, these are federally required processes that must be met in order for the patient to obtain the medication. These programs are often administered by third party entities to ensure compliance. Other healthcare providers may have the following responsibilities related to REMS programs.

  Health care providers with prescribing privileges (e.g., physicians, physician's assistants, nurse practitioners or other health care providers) play a key role in ensuring products with serious risks requiring REMS are prescribed and used safely. The requirements for providers will vary for each REMS. For most REMS, providers may receive REMS communications from the manufacturers. Certain REMS may require the provider to enroll in the REMS, complete training, document counseling of patients, enroll patients, perform monitoring and/or document compliance with certain safe use conditions.

  Some REMS require patient, prescriber and/or pharmacy enrollment. Enrollment is used to keep track of the patients receiving the medication, required documentation, laboratory results and/or adverse events or patient outcomes. Health care providers (or their designee) generally enroll patients. Depending on the program, this may require completion and submission of a form, either by mail, fax, online or by telephoning a contact center.

  Certain REMS medications can only be dispensed in specific healthcare settings, such as hospitals or infusion centers. For example, Lemtrada® (a medication used for Multiple Sclerosis) is restricted to hospitals or infusion centers because of the risk of serious and life-threatening infusion reactions. Certain REMS may require the pharmacies and/or prescribers to become certified. Sabril® (vigabatrin), an anticonvulsant, is currently only available in an inpatient setting or from pharmacies that are able to comply with the REMS requirements. Healthcare providers and patients should check the individual REMS to confirm how to obtain the medication.

- Switch/Service Intermediary

  The role of an intermediary is to facilitate the routing of benefit investigation transactions across their network connecting various industry stakeholders electronically. Communication of accurate and timely benefit information is a key component of switch functionality. When electronic processes do not exist between business partners then some intermediaries may offer other solutions for communication. Enhancing the transactions that are existing and promoting newer standards will provide a more complete way for industry stakeholders to leverage intermediaries.

- Pharmacy software systems (Pharmacy System Vendor)

Pharmacy software systems are a key component of benefit investigation for specialty pharmacies. These systems maintain patient information, including demographics, insurance data and clinical information (medications dispensed, allergies, etc.). They provide the capability to perform NCPDP E1 eligibility transactions allowing to validate either commercial insurance or Medicare Part B or Part D coverage. Most systems do not support medical benefit verification and a portal may have to be used in addition the pharmacy software system. Finally, pharmacy software systems support claims adjudication and many also support electronic prior authorizations.

- Hub Solutions
  Hub solutions have arisen partially due to the complexity of getting patient access to specialty medications. Hub responsibilities include eligibility inquiry, manufacturer feedback and completion of any prior authorization that may be required. One of the goals for the hub is to determine the benefit that is most advantageous to the patient. In addition to querying both benefits to determine the best outcome the hub will also work through other barriers to therapy. Hubs also work through issues such as patient assistance programs, pharmacy access and logistical issues of getting the medication for the patient. These hub functions come together to find the combination of benefits and other assistance that are best for the patient.

6.2 CURRENT TECHNICAL SOLUTIONS

There is a need to optimize the technical solutions being used in order to streamline benefit identification. Described below are some of the opportunities to improve some of these technical solutions.

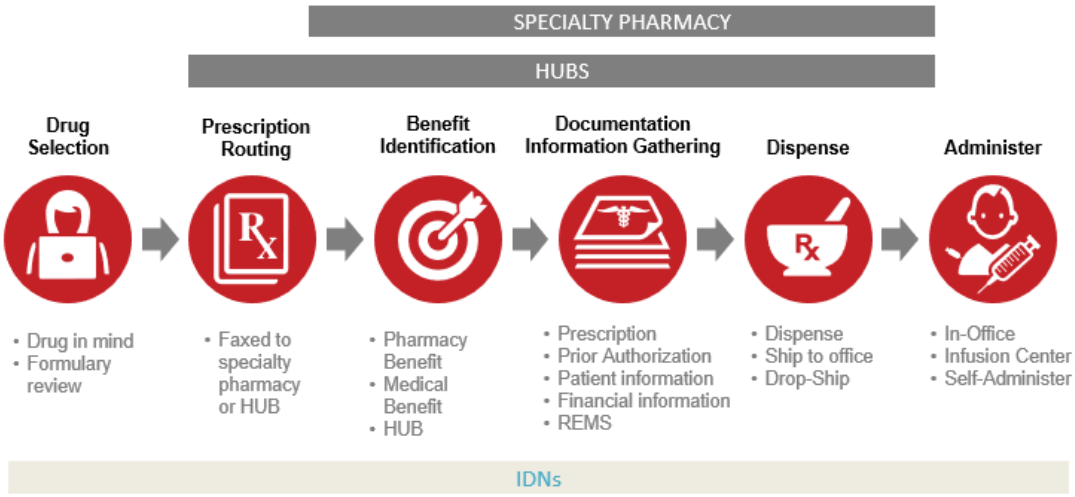
1. e-Prescribing tools such as Formulary and Benefit files and RTPB transactions can be more widely adopted and drive clarity around the pharmacy benefit as well as enhancements that have been made to more fully communicate medical benefit information.
2. Updating X12 270/271 transactions so that minimum data elements would allow payers to identify both pharmacy and medical benefit coverage including: Payer Name, Payer ID, BIN/IIN, PCN, Group, Cardholder, etc. This enhanced information will centralize coverage details in a single point and be directly linked to the patient's EHR profile.
3. Maximizing the eligibility transaction to identify all coverages – Medicare, Commercial, Medicaid, etc. in a single BI (Benefit Investigation) transaction, linked to the patient's profile.
4. Leverage Real-Time Prescription Benefit Standard transactions which provide patient specific pharmacy benefit information. This information would provide a provider with maximum amount of information and best process to gain approval for a specialty medication, so the patient is able to start or continue therapy without delay.
5. HL7 (FHIR®) based solutions utilizing open APIs allowing open querying of data for various actors in the process.

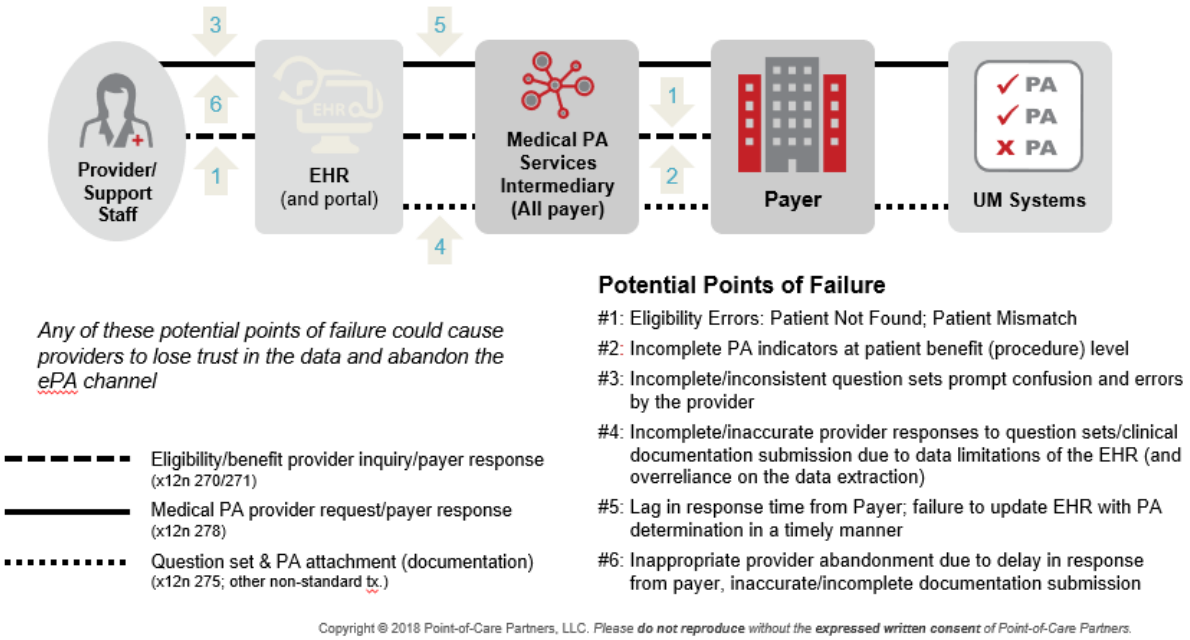
Technical Solution	**Payer Role**	**Prescriber/Provider Role**	**Other Role**
Formulary and Benefit Standard	Fully populate F&B files. Update	Leverage F&B files supplied by payer to guide product	Hub – N/A Pharmacy – N/A

Technical Solution	Payer Role	Prescriber/Provider Role	Other Role
	to next version when named.	selection to ensure formulary compliance. Ensure all providers are trained/aware of available content. Update to next version when named.	
270/271	Provide accurate and complete benefit information based on information received on request.	Utilize patient specific benefit information received.	Hub – same as prescriber/provider. Pharmacy – N/A
RTPB Standard	Respond with complete information, including which benefit will cover the requested product.	Submit request and utilize patient specific benefit information received. Communicate with patient regarding response to determine optimal benefit. Use decision support to provide cost-effective medication therapy.	Hub – same as prescriber/provider. Pharmacy – same as prescriber/provider.
HL7 APIs	Utilize FHIR® and other message types to communicate clinical and financial information.	Allows proprietary information to be used at the point of care	

The workflows shown below highlight where users need to go for benefit information. Potential points of failure identify where current solutions need to be optimized.

Intersection of Pharmacy and Medical Benefits





6.3 *REGULATORY REQUIREMENTS THAT AFFECT BENEFIT IDENTIFICATION*

Benefit	Standard	Rule	Requirement
Medical	X12 270/271	Health Insurance Portability and Accountability Act (HIPAA)	Mandated use of X12 270/271 to determine eligibility for medical benefits. The X12 271 Eligibility Response indicates that the information source (payer) may support this.
Pharmacy	X12 270/271	Medicare Modernization Act (MMA)	Mandated use of X12 270/271 to determine eligibility for pharmacy benefits. The X12 270 Eligibility Request allows the ability to inquire about a particular National Drug Code (NDC) at the patient level.
Pharmacy		CMS' Modernizing Part D and Medicare Advantage to Lower	Covers many general specialty medication pricing issues in Medicare Advantage and Medicare Part D. Part of

Benefit	Standard	Rule	Requirement
		Drug Prices and Reduce Out-of-Pocket Expenses (84 FR 23832)	the final rule is designed to encourage the use of Real-Time Benefit Tools (RTBTs) by requiring that by January 1, 2021, each Part D plan must adopt at least one RTBT that is capable of integrating with at least one provider's EHR or ePrescribing system.
Prior Authorization for Part D or MA-PD Covered Drugs	NCPDP SCRIPT *(proposed)*	SUPPORT for Patients and Communities Act	The effective date for all plans to accept prior authorizations for Part D or MA-PD covered drugs electronically has been delayed and is unknown at the time of this white paper's publication. In the 2019 proposed rule, NCPDP SCRIPT 2017071 was named as the standard to be used, but the final rule has not been published at the time of this white paper's publication. The X12 278 must still be used for medications covered under the medical benefit and for non-Part D plans for those medications covered under the pharmacy benefit.

With the rise in utilization of specialty medications, we expect additional rulemaking within the annual rules that CMS promulgates in order to update policies as needed and in response to new legislation.

7 UNDERSTANDING THE COMPLEXITIES IN DETERMINING BENEFIT COVERAGE FOR SPECIALTY PHARMACY

Specialty pharmaceuticals are complex, high cost and, in many cases, lifesaving. This trifecta of complexity, urgency and cost means these specialty medications must be filled with the utmost skill, speed and accuracy. The table below summarizes some common examples in the Specialty Pharmacy industry that drive complexity. The current best practices for initial benefit identification are laid out alongside the examples.

				Current Best Practice Initial Benefit Identification Methods			
Category	**Medical or Pharmacy Benefit?**	**Examples**	**Typical Site of Care**	**Ambulatory Practice Setting**	**Complex/Integrated Delivery Network (IDN) Self Service**	**Ambulatory Hub Services**	**Complex/IDN Hub Services**
High Cost Oral Specialty Medication	Pharmacy	Anti-coagulants Oncology HIV	Home based	e-Prescribing Process	e-Prescribing Process	Fax to Hub	Medical X12 270
Injectables	Pharmacy	Subcutaneous	Home based	e-Prescribing Process	e-Prescribing Process	Fax to Hub	Medical X12 270
Injectables	Medical	IV/IM	Home based or Ambulatory infusion site	e-Prescribing Process, Medical X12 270	e-Prescribing Process, Medical X12 270	Fax to Hub	Medical X12 270
Inhalation	Could be either	Nebulizer solution or device, Oral Inhaler Device	Home based	e-Prescribing Process	e-Prescribing Process	Fax to Hub	Medical X12 270
Topicals	Pharmacy	Ointment, patches	Home based	e-Prescribing Process	e-Prescribing Process		Medical X12 270
Nuclear pharmaceuticals	Medical	Radioactive beads	Hospital inpatient or Ambulatory infusion site	Medical X12 270	Medical X12 270	Fax to Hub	Medical X12 270

				Current Best Practice Initial Benefit Identification Methods			
Category	**Medical or Pharmacy Benefit?**	**Examples**	**Typical Site of Care**	**Ambulatory Practice Setting**	**Complex/Integrated Delivery Network (IDN) Self Service**	**Ambulatory Hub Services**	**Complex/IDN Hub Services**
Fertility	Could be either	Fertility Medications	Clinic or Hospital outpatient	e-Prescribing Process	e-Prescribing Process	Fax to Hub	Medical X12 270
Oncology & Transplant	Could be either	Chemotherapy	Home based, Hospital inpatient or ambulatory infusion site	e-Prescribing Process	e-Prescribing Process	Fax to Hub	Medical X12 270
PAH & Hemophilia	Both	Von Willebrand	Home based, Hospital inpatient or ambulatory infusion site	e-Prescribing Process	e-Prescribing Process	Fax to Hub	Medical X12 270

8 CRITICAL SUCCESS FACTORS

The key to moving the specialty pharmacy industry forward with benefit identification is a multifaceted solution. Allowing all parties involved to know exactly what benefit is most advantageous for the patient should drive key process indicators of success. The current state is challenging because the information is not readily available for all parties. Streamlining the availability of eligibility data so that all players in the process can access and more efficiently process specialty patient prescriptions will move the industry forward. Below are other key process improvement metrics that will need to be addressed.

8.1 INTEROPERABILITY ACCORDING TO HEALTHCARE INFORMATION AND MANAGEMENT SYSTEMS SOCIETY (HIMSS)

Interoperability, according to Healthcare Information and Management Systems Society (HIMSS), is the ability of different information systems, devices and applications to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries to provide timely and seamless portability of information and optimize the health of individuals and populations globally. Standards enable data to be accessed and shared appropriately and securely across the complete spectrum of care, within all applicable settings and with relevant stakeholders.

8.2 QUALITY OF THE DATA

Just as having accurate data parameters is critical for accurate patient diagnosis, the same goes for benefit identification. In a healthcare ecosystem where more and more financial burden falls on the patient, maximizing the benefit to ensure access and compliance with the prescribed regimen is critical. Utilizing standards can aid in ensuring quality data is supplied between healthcare providers. The next step is to capture and map out all information needed to provide a complete picture of the medical and pharmacy benefit for each patient.

Healthcare seems to be an industry where data passed in transactions between providers is viewed as an administrative burden. Unlike other industries, data quality is not the main focus of many healthcare transactions including benefit identification. That viewpoint needs to change from minimum viable data to prevent a transaction from erroring to maximum benefit for the patient. Some examples of data quality that can be improved in the short term for better interoperability include:

1. Pharmacy Benefit Eligibility
    a. Is the data current?
        i. Depending on sender software system, there may be limitations for what is requested in eligibility transaction
        Example: Requesting Medicare coverage data without commercial or Medicaid information
    b. Primary coverage vs secondary coverage
        i. Completeness of data being passed to identify who is primary vs. secondary for the pharmacy benefit
2. Medical Benefit Eligibility
    a. Is the data current?
        i. Depending on sender software system, there may be limitations for what is requested in eligibility transaction

b. Is there a secondary payer?
    i. Is the pharmacy contracted
        1. Many times, under the medical benefit, a pharmacy may not be contracted

8.3 AVAILABILITY OF THE DATA

Despite the widespread availability of secure electronic data transfer, most Americans' benefit information is stored on paper or in electronic medical records that cannot communicate seamlessly with other systems. When that benefit information is shared between providers, it mostly happens by phone, portal, fax or even mail.

Communication challenges between payers, intermediaries and providers exist today making data unavailable to all parties. Part of the problem is incomplete adoption of a full standard for sharing benefit information. Where adoption has occurred nuances from one payer to another make it difficult to allow a free flow of information across the healthcare spectrum. There is functionality available in standards such as the X12 270/271 that would allow for easy identification of a provider and the details needed per the request. Furthermore, details of types of procedures could be conveyed using the X12 278 making medical benefit information more detailed and easily shared. These changes coming in a newer version of the X12 278 standard will make data exchange more robust and stakeholders are encouraged to move quickly to adopt these changes.

8.4 ADOPTION

In order to seamlessly exchange and understand data, adoption of multiple standards that support benefit investigation is required. Adoption of standards is typically slow unless mandated in some form of regulation. Many information technology (IT) systems have been developed as stand-alone applications serving specific purposes only. First, clear standards and data sets need to be defined for benefit identification. Once that is in place, organizations such as NCPDP and others may need to develop operating rules for widespread industry adoption of such standards.

Critical components for adoption will be:

- Agreeing upon the minimum data sets necessary to be shared between stakeholders
- Understanding gaps in current standards
- Identifying how to leverage existing standards capabilities
- Create coordinated progress amongst industry stakeholders
- Identify areas for industry collaboration to move benefit identification forward

8.5 COST

With the advent of more vertically integrated payer models in the marketplace, it does seem like the ability to monitor medical and pharmacy benefits would be more possible than ever. However, even with such models, certain benefits are carved out or have confounding circumstances making benefit identification unclear.

The specialty pharmacy market now constitutes almost 50% of total drug spend in the United States. The ability to accurately assess the cost of therapy to the patient has enormous impacts on patients and

payers. Given that the largest payer overall is taxpayers means the impact is societal in nature. Ensuring the most appropriate benefit in terms of cost a vital success factor of benefit identification.

9 TIMELINE/IMPLEMENTATION

The implementation timeline will be dependent on several key factors including adoption of real-time medical and pharmacy transactions by vendors to interoperability of quality data. Organizations are moving forward to implement these solutions to improve time to therapy for their patients on specialty medications.

10 CONCLUSIONS/NEXT STEPS

The intent and goal of this white paper is to call out the current challenges experienced by various healthcare professionals (i.e., medical providers, specialty pharmacies, hubs, etc.) in being able to accurately identify if a specialty medication is covered under a patient's medical or pharmacy benefit. There are currently minimal and inconsistent standardizations across multiple resources that clearly provide this information. These challenges and lack of comprehensive benefit information can greatly affect a patient's out-of-pocket costs and their ability to begin necessary therapy in a timely manner.

As identified in this white paper, the key to moving the specialty pharmacy industry forward with benefit identification is a multifaceted solution. It will require the three standards development organizations (NCPDP, X12 and HL7) to work together toward a solution. Education of key industry leaders and policymakers of the challenges involved is critical in developing solutions to improve access to reliable, consistent and accurate medical or pharmacy benefit information, specific to an individual patient's insurance plan. This access to transparent and complete benefit information will reduce delays to therapy, improve provider-patient interaction, provide up-front information about a patient's coverage at the time the specialty medication is selected, determine a patient's out-of-pocket costs and reduce provider/pharmacy workloads.

11 APPENDIX A: GLOSSARY

Electronic Health Record (EHR) Vendor

An entity that provides software and perhaps hardware to physicians, clinics, hospitals, whose purpose is to build, maintain and share [where appropriate] a patient's clinical medical record.

Formulary

Lists of drugs published to help physicians reach clinically and economically appropriate prescribing decisions for patients.

Healthcare Common Procedural Coding System (HCPCS)

Standardized coding system for describing the specific items and services provided in the delivery of health care. Also known as "hick picks."

Health System

A health system, also sometimes referred to as health care system or as healthcare system, is the organization of people, institutions and resources that deliver health care services to meet the health needs of target populations.

Hub

Hub services are manufacturer sponsored programs that assist patients and providers in the areas of access, affordability and adherence services.

Payer

An entity that is either financially responsible or remits financial reimbursement of goods and/or services. A “PAYER” is often a third-party administrator of prescription drug programs on behalf of insurers. The payer also may be an insurer, a governmental program or any other entity which receives prescription drug claims. The payer may be for medical, pharmacy or both benefit(s).

Pharmacy

A licensed entity that dispenses prescription drugs and provides professional pharmacy services, such as clinical pharmacy services (consulting) respective to the dispensing function.

Pharmacy Benefit Manager (PBM)

Administers prescription drug programs, as well as managing costs for a plan sponsor to achieve the most effective utilization of prescription drug expenditures, such as benefit design, formulary management, rebate contracting, retrospective Drug Use Review (DUR), prospective DUR, network administration, disease state management and so forth.

Pharmacy Software System (Pharmacy System Vendor)

An entity that provides software and perhaps hardware to pharmacies or prescribers that enables electronic processing of business functions such as electronic prescribing, electronic medical records, appointments and scheduling and billing functions.

Prescriber

A licensed entity that prescribes prescription drugs and provides professional medical services, such as clinical services respective to the prescribing function. The entity may be a clinic or independent prescriber, hospital or care facility.

Prior Authorization (PA)

Prior Authorization (PA) is the process that requires specific authorization from a "Payer" (health plan, processor or Pharmacy Benefit Manager) to dispense a medication based on a number of factors, such as medical necessity, prior treatment options and clinical qualifiers.

Health plans place PA requirements on select drugs to encourage appropriate clinical usage and to manage costs of expensive therapy.

Provider

An individual or entity that renders medical or health care services or products.

Risk Evaluation and Mitigation Strategies (REMS)

"A drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to help reduce the occurrence and/or severity of certain serious risks, by informing and/or supporting the execution of the safe use conditions described in the medication's FDA-approved prescribing information."[3]

Specialty Pharmacy

A specialty pharmacy is a state-licensed pharmacy that solely or largely provides only medications for people with serious health conditions requiring complex therapies.[4]

Switch/Service Intermediary

An entity that accepts an electronic transaction from another organization and electronically routes the transaction to a receiving entity. A switch/intermediary may perform value added services including detailed editing/messaging of input/output data for validity and accuracy and translating data from one format to another.

[3] Source: https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems
[4] Source: http://naspnet.org/wp-content/uploads/2017/02/NASP-Defintions-final-2.16.pdf

12 APPENDIX B: RESOURCES

CMS Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses (84 FR 23832) - This final rule amends the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to support health and drug plans' negotiation for lower drug prices and reduce out-of-pocket costs for Part C and D enrollees. These amendments will improve the regulatory framework to facilitate development of Part C and Part D products that better meet the individual beneficiary's healthcare needs and reduce out-of-pocket spending for enrollees at the pharmacy and other sites of care.

The Health Insurance Portability and Accountability Act HIPAA - a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge.

HL7 - American National Standards Institute (ANSI)-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.

Medicare Prescription Drug Improvement and Modernization Act (aka Medicare Modernization Act (MMA)) – Amended title XVIII (Medicare) of the Social Security Act (SSA) to add a new part D (Voluntary Prescription Drug Benefit Program). NCPDP's SCRIPT and Formulary & Benefit Standards and X12's 270/271 transactions are named in the MMA.

NCPDP - ANSI-accredited Standards Development Organization (SDO), NCPDP uses a consensus-building process to create national standards for real-time, electronic exchange of healthcare information. NCPDP's primary focus is on information exchange for prescribing, dispensing, monitoring, managing and paying for medications and pharmacy services crucial to quality healthcare.

Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act in 2018 - Provides for opioid use disorder prevention, recovery, treatment and for other purposes.

X12 - Chartered by ANSI for more than 35 years, develops and maintains EDI standards and XML schemas which drive business processes globally. The X12N Subcommittee is focused on health care: X12N is responsible for the development and maintenance of components of the X12 EDI Standards related to the insurance industry's business activities, including those related to property insurance, casualty insurance, health care insurance, life insurance, annuity insurance, reinsurance and pensions.

13 APPENDIX C: DOCUMENT REVISIONS

Version 10

- Original Publication

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