



November 6, 2020

Shelly Winston
Medicare Drug Benefit and C & D Data Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard, C1-26-05
Baltimore, MD 21244
Sent via electronic mail

RE: 42 CFR § 423.160 Standards for Electronic Prescribing (b) Standards (5) Formulary and Benefits

The members of the National Council for Prescription Drug Programs (NCPDP) are requesting via an appropriate rulemaking process the adoption of the NCPDP Formulary and Benefit Standard Version 53 in 42 CFR § 423.160 Standards for Electronic Prescribing (b) Standards (5) Formulary and Benefits. The NCPDP Formulary and Benefit Standard Version 53 would replace the currently named NCPDP Formulary and Benefit Standard Version 3.0.

The Formulary and Benefit Standard has been updated to meet industry need and current usage. All list (files) have been normalized, which allows for smaller files and reusability, and have expiration dates. The alternative and step medication files have been redesigned to reduce file sizes and to include support for reason for use (diagnosis). The step medication files now support a more complex step medication program. Coverage files have been updated to include support for electronic prior authorization and specialty drugs. The copay files have been updated to allow a minimum and maximum copay range without a percent copay. They also have support for benefit stage copay/deductibles, pharmacy network support, Medicare Part D support and approximate drug cost. A comprehensive change log is attached.

The members are also requesting the following timeline be adopted.

- 5 months after the final rule is published – start of transition period where both versions are allowed
- 22 months after the final rule is published – sunset of the Formulary and Benefit Standard Version 3.0
- 23 months after the final rule is published – mandated use of the Formulary and Benefit Standard Version 53

For direct inquiries or questions related to this request, please contact:

Margaret Weiker
Vice President Standards Development, NCPDP
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Sincerely,

A handwritten signature in black ink, appearing to read "Shelly Winston". The signature is written in a cursive, flowing style.

Lee Ann C. Stember President & CEO
National Council for Prescription Drug Programs (NCPDP)
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Attachment: Formulary and Benefit Standard Change Log

FORMULARY AND BENEFIT STANDARD CHANGE LOG SINCE V3.0

VERSION 4.0, JANUARY 2013

For standardization,

- Source Name (972-JK) field size was modified from 35 to 70 bytes.

Diagnosis Code Qualifier (492-WE) removed values of 06 (Medi-Span Product Line Diagnosis Code), 08 (First DataBank Disease Code (FDBDX)), 09 First DataBank FML Disease Identifier (FDB DxID) and 99 (Other).

Figure 2. Formulary And Benefit Summary Information Model had a designation of (+1) on some balloons and not on others and wasn't explained. The (+1) has been removed as the verbiage of the document explains the usage better.

VERSION 4.1, SEPTEMBER 2013

Figure 2 was updated to reflect the addition of the Electronic Prior Authorization Routing Coverage Type and the removal of the Prior Authorization List files.

The Message – Short (942-GP) was modified to Required “Yes”.

The following fields were sunsetted and removed from the layouts as well as associated examples:

- Relative Cost (966-JC) removed from the Formulary Status Detail
- Relative Cost Limit (967-JD) removed from the Formulary Status Header
- Class ID - Step Drug (903-BR) and Subclass ID – Step Drug (976-JQ) removed from the Coverage Information Detail – Step Medication (SM)
 - This removed example “Coverage- Step Medication in Terms of Drug Class”.

The following Prior Authorization List Files (Header, Detail and Trailer Records) and associated examples have been removed:

- Prior Authorization Form List
- Prior Authorization Drug ID Form List
- Prior Authorization Question List
- Prior Authorization Applicability List
- Prior Authorization Answer List

These have been removed in favor of the electronic prior authorization transactions now available in the NCPDP SCRIPT Implementation Guide version 2013+.

The following fields were sunsetted as a result of the removal of the Prior Authorization List Files:

- Prior Authorization Form ID (657-T5)
- Prior Authorization Form Title (658-T6)
- Prior Authorization Question Code (659-T7)
- Prior Authorization Question Code Qualifier (660-T8)
- Prior Authorization Question Sequence (661-T9)
- Prior Authorization Question Number (662-V1)
- Prior Authorization Applicability (663-V2)
- Prior Authorization Required Question (664-V3)
- Prior Authorization Response Type (665-V4)

- Prior Authorization Question Text (665-V5)
- Prior Authorization Basis Question Sequence Number (667-V6)
- Prior Authorization Comparison Type (668-V7)
- Prior Authorization Basis Value (669-V8)
- Prior Authorization Answer Value (670-V9)

Corrected inconsistency with the addition of decimal 126 to the printable characters values in “Character Set Designation”.

Clarified the use of a decimal point for Numeric 0-9 with decimal point in section “Numeric 0-9 With Decimal Point”.

A new coverage type was added for electronic Prior Authorization Routing information.

Additional RxNorm Qualifier (970-JH) values were added to the External Code List - BN (Brand Name), IN (Ingredient (generic name)), PIN (Precise Ingredient (generic name)), MIN (Multi-ingredient (generic name)), SCF (Semantic Clinical Drug Form), SBF (Semantic Branded Drug Form).

VERSION 42, OCTOBER 2014

Section “Version Identification System” was updated with language approved in DERF 001167.

Copay Information Detail – Summary Level (SL) – modified Product Type (964-JA) values in the External Code List

“0” (Not specified) – value may not be used

“2” (Authorized Generic AKA “Branded Generic”) – value sunsetted

“5” (Compound) – value sunsetted

“A” (Any) – value clarified to “Copay is consistent across all product types within a specific formulary status.”

Also, a paragraph was added after the layout to explain that copay summary records are mutually exclusive. See “Copay Information Detail – Summary Level (SL)”.

Pharmacy Type (955–HR) is mandatory in the Copay Information Detail – Drug-Specific (DS) file.

If a payer uses a Percent Copay Rate (954-HQ), the Minimum Copay (945-GS) and Maximum Copay (9390GK) are not required. Minimum Copay (945-GS) and Maximum Copay (939-GK) added “may only be used” to the Required column, and “Not required if a percent copay rate is used” in the Comments column. See “Copay Information Detail – Drug Specific (DS)”.

Step Medications specification contained an artifact from the removed Drug Classification Lists. Drug Qualifier - Step Drug (914-B5) is no longer relevant. Originally it indicated whether the Step Medications alternatives would be provided by NDC/other specific drug identifier or by Pharmacological Class (PC). PC indicates that the step therapy list is defined by a therapy class of drugs vs. a specific drug. All step medication drugs are now drug specific. Drug Qualifier - Step Drug (914-B5) was removed from Coverage Information Detail – Step Medications (SG) Groups.

Number of Drugs to Try (951-GY) had a comment that referred to the above field - “Mandatory if Drug Qualifier - Step Drug = PC” The comment was removed. The field was made mandatory.

The layout of the Alternatives and Step Medications files normalized the layouts of both file types to reduce file size and enhances step medication logic. The modification breaks out the files into two sets: a trigger file that identifies which drug needs to be selected as a trigger and the second file is used to define the drug group that needs to be displayed. The layout reduces the file size by allowing trigger drugs to call upon the same drug groups. The net effect is a reduction in file size. Sections “Payer-Specified Alternatives”, “Flow Three: Presenting Formulary Alternatives”, “Transmission Level From The Sender To The Receiver” were updated. References to “off-formulary” were clarified to “indicated”.

Additional enhancements have been added to the Step Meds files:

1. Support of conditional step med groups. This enhancement allows payers to let prescribers know that they may select 0 or more drugs from a number of step med groups. A prescriber may only need two drugs from three or more step groups so the proposed logic supports this requirement.
2. Support for preference levels in the step med groups (similar to alternatives). Payers may now specify the order step drugs appear in each step medications group.

Alternatives List Type (B63-1N) was added to Formulary Alternatives Header.

Formulary Alternatives Detail was renamed to Formulary Alternatives Triggers.

Alternatives Group ID (B62-1M) was added.

Product/Service ID - Alternative (958-HU), Product/Service ID Qualifier – Alternative (959-HV), Drug Reference Number – Alternative (917-B8), Drug Reference Qualifier – Alternative (918-B9), RxNorm Code (969-JG), RxNorm Qualifier (970-JH), and Preference Level (956-HS) were moved to Formulary Alternatives Groups.

Formulary Alternatives Groups was added.

Coverage Information Detail - Step Medications (SM) Triggers added Triggers to the name.

Step Medications Groups ID (B64-1P), Number of Drugs To Try (951-GY), Minimum Drugs Per Step Group (B65-3M), Maximum Drugs Per Step Group (B66-3N), Step Order (974-JN), Diagnosis Code (424-DO), and Diagnosis Code Qualifier (492-WE) were added.

Coverage Information Detail - Step Medications (SG) Groups was added. Minimum Drugs Per Step Group (B65-3M), Maximum Drugs Per Step Group (B66-3N) removed the comment “Not used for alternatives.”

Coverage Information Detail – Electronic Prior Authorization Detail was renamed to Coverage Information Detail – Electronic Prior Authorization Processor Detail (PR) and a value of “PR” was given for Coverage List Type (912-B3).

Figure 2. Formulary And Benefit Summary Information Model was updated. Examples were updated.

VERSION 43, JANUARY 2015

Copay Information Detail – Summary Level (SL) and Drug Specific (DS) records removed the conditionality from the Minimum Copay (945-GS) and Maximum Copay (939-GK) fields and adjusted the conditionality of the Flat Copay Amount (925-ES) and Percent Copay Rate (954-HQ). These fields could not be submitted without populating the Percent Copay Rate field. This change allows formulary providers to submit these fields alone.

925-ES	FLAT COPAY AMOUNT	R 1/10	Conditional - at least one of the following fields must be populated: Flat	This amount is additional to Percent Copay Rate if populated.
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			<p>Copay Amount, Percent Copay Rate, or Copay Tier</p> <p>To</p> <p>Conditional - at least one of the following fields must be populated: Flat Copay Amount, Percent Copay Rate, Copay Tier, or Minimum or Maximum Copay. May not be used if Minimum or Maximum Copay is used.</p>	<p>No dollar sign. Decimal required if value includes cents.</p> <p>The length includes the decimal point.</p> <p>Currency: USD</p>
954-HQ	PERCENT COPAY RATE	R 1/10	<p>Conditional - at least one of the following fields must be populated: Flat Copay Amount, Percent Copay Rate, or Copay Tier</p> <p>To</p> <p>Conditional - at least one of the following fields must be populated: Flat Copay Amount, Percent Copay Rate, Copay Tier, or Minimum or Maximum Copay.</p>	<p>This amount is additional to Flat Copay Amount if populated.</p> <p>Percentage expressed as a decimal (e.g., 0.0 through 1.0 represents 0% through 100%)</p> <p>The length includes the decimal point.</p>
924-DH	FIRST COPAY TERM	AN 1/1	<p>Conditional - if both Flat Copay Amount and Percent Copay Rate are populated</p> <p>To</p> <p>Conditional - if both Flat Copay Amount or Minimum or Maximum Copay and Percent Copay Rate are populated.</p>	<p><i>Values: See External Code List</i></p>
945-GS	MINIMUM COPAY	C 1/10	<p>Conditional - if Percent Copay Rate is populated</p> <p>To</p> <p>Conditional - at least one of the following fields must be populated: Percent Copay Rate, Copay Tier, or Minimum or Maximum Copay.</p>	<p>No dollar sign. Decimal required if value includes cents. Currency: USD</p> <p>The length includes the decimal point.</p>

939-GK	MAXIMUM COPAY	C 1/10	Conditional - if Percent Copay Rate is populated To Conditional - at least one of the following fields must be populated: Percent Copay Rate, Copay Tier, or Minimum or Maximum Copay.	No dollar sign. Decimal required if value includes cents. Currency: USD The length includes the decimal point.
988-MB	DAYS SUPPLY PER COPAY	N 1/3	No	
909-BX	COPAY TIER	N 1/2	Conditional - at least one of the following fields must be populated: Flat Copay Amount, Percent Copay Rate, Copay Tier, or Minimum or Maximum Copay.	The Copay Tier value may not be greater than the Maximum Copay Tier value
940-GM	MAXIMUM COPAY TIER	N 1/2	Conditional - if Copay Tier is populated.	

Section “*Frequently Asked Questions*”, “Using Percent Copay and the Min/Max Copay Amounts” was added.

This version also modifies the description in the External Code List for First Copay Term (924-DH) value “F” (Flat Copay: “A code indicating the patient responsibility is based on a preset value or value range for the corresponding drug type).

Section “Representative NDC” was clarified to add:

In order to maximize the opportunity that the selected NDC exists among the various drug files, a representative NDC **should be a nationally available product** and should not be a repackaged NDC, obsolete NDC, private label NDC or unit dose NDC unless it is the only NDC available identifying that category of medication. **When exchanged, the drug description of the product must match the description of the representative NDC code value.**

An editorial correction was made to the diagram in section “Transmission Level from the Sender to the Receiver” to move “Coverage List ID (911-BZ) = BBBB” from Coverage Information Trailer to Coverage Information Header where it belonged.

VERSION 44, OCTOBER 2015

New field List Expiration Date (B93-3Y) added to sections Formulary Status Header, Cross Reference List Header, Formulary Alternatives Header, Copay Information Header, Copay List and Coverage Information Header.

New value of Specialty (SD) added to section Coverage Information Detail. Added footnote explaining specialty drug.

An editorial correction was made to move everything under Section: Coverage Information Detail Coverage Text Message and Benefit Copay List back under Section: Transmission from Sender to Receiver Structure causing a renumbering of all sections that follow.

VERSION 50, OCTOBER 2016

New Data Elements Added:
Age Limits ID (C03-1A)
Benefit Stage Range End (C04-1B)
Benefit Stage Range End Qualifier (C05-4Q)
Benefit Stage Range Start (C06-4R)
Benefit Stage Range Start Qualifier (C07-4S)
Conditional Gender Code (C08-4T)
Conditional Maximum Age Limit (C09-4Y)
Conditional Maximum Age Limit Qualifier (C10-4Z)
Conditional Minimum Age Limit (C11-5D)
Conditional Minimum Age Limit Qualifier (C12-6H)
Copay Product Specific ID (C13-6J)
Copay Summary ID (C14-6K)
Cross Reference File ID (C17-6P)
Cross Reference ID (C15-6M)
Formulary Copay Price Point (C16-6N)
Gender Limits ID (C18-6Q)
General Message ID (C19-6R)
General Message Link (C20-6S)
Lives Count (C21-6T)
Maximum Days Supply (C22-6U)
Maximum RRA Fill Limit (C23-6V)
Maximum Unit Quantity (C24-6W)

New Data Elements Added:
Message ID (C25-6X)
Message Link (C26-6Y)
Minimum RRA Fill Limit (C27-6Z)
Minimum Unit Quantity (C28-8V)
Non-Listed LTC Pharmacy Status (C29-8W)
Non-Listed Mail Pharmacy Status (C30-8X)
Non-Listed Multi-Source Brand Formulary Status (C31-8Y)
Non-Listed Retail Pharmacy Status (C32-8Z)
Non-Listed Specialty Pharmacy Status (C33-9B)
PA Processor Name (C34-9C)
Pharmacy ID (C36-9E)
Pharmacy Chain ID (C35-9D)
Pharmacy Network ID (C37-9G)
Pharmacy Network Status (C38-9H)
Prior Authorization ID (C39-9J)
Product Exclusion ID (C40-9K)
Quantity Limits ID (C41-9M)
Specialty Product Benefit Indicator (C42-9N)
Specialty Products ID (C43-9P)
Step Products Group ID (C44-9Q)
Step Therapy ID (C45-9R)
URL Text (C46-9S)

Modified Data Elements:**1. Existing data elements with a Name Change: (Note: Definitions, size or comments may have also changed)**

Field Tag	Original Name	New Name
B63-1N	Alternatives List Type	Alternatives File Type
915-B6	Drug Reference Number	Product Reference Number
917-B8	Drug Reference Number – Alternative	Product Reference Number – Alternative
922-CV	Drug Reference Qualifier - Step Drug	Product Reference Qualifier – Step Product
919-CS	Drug Reference Number – Source	Product Reference Number – Source
921-CU	Drug Reference Number – Step Drug	Product Reference Number – Step Product
916-B7	Drug Reference Qualifier	Product Reference Qualifier
918-B9	Drug Reference Qualifier – Alternative	Product Reference Qualifier - Alternate
920-CT	Drug Reference Qualifier – Source	Product Reference Qualifier - Source
928-FR	List Action	File Action
929-FZ	List Effective Date	File Effective Date
B93-3Y	List Expiration Date	File Expiration Date
B66-3N	Maximum Drugs Per Step Group	Maximum Products Per Step Group
942-GP	Message-Short	Message
B65-3M	Minimum Drugs Per Step Group	Minimum Products Per Step Group
946-GT	Non-listed Prescription Brand Formulary Status	Non-Listed Single Source Brand Formulary Status
951-GY	Number of Drugs To Try	Number of Products To Try
957-HT	Product Name-Health Plan	Health Plan Product Name
961-HX	Product/Service ID Qualifier-Step Drug	Product/Service ID Qualifier-Step Product

2. Existing data elements with definitions, sizes or comments modified:

- 901-BP Alternatives ID
- 926-FF Formulary ID
- 927-FP Formulary Status
- 947-GU Non-Listed Prescription Generic Formulary Status
- 950-GX Non-Listed Supplies Formulary
- 956-HS Preference Level
- 201-B1 Service Provider ID (Added to Formulary and Benefit)
- 202-B2 Service Provider ID Qualifier (Added to Formulary and Benefit)
- 987-MA URL

3. Sunsetting Data Elements:

- 906-BU Copay ID
- 907-BV Copay List ID
- 908-BW Copay List Type
- 910-BY Coverage ID
- 911-BZ Coverage List ID
- 941-GN Message-Long
- 968-JF Resource Link Type
- A46-1S Text Message Type

New Files:

- Alternatives Group (AG) Header and Trailer
- Copay Summary (CS) Header, Detail and Trailer
- Copay Product Specific (CP) Header, Detail and Trailer
- Product Exclusion (PE) Header, Detail and Trailer
- Age Limit (AL) Header, Detail and Trailer
- Gender Limit (GL) Header, Detail and Trailer
- Quantity Limits (QL) Header, Detail and Trailer
- Prior Authorization (PA) Header, Detail and Trailer
- Specialty Products (SP) Header, Detail and Trailer
- Step Therapy (ST) Header, Detail, and Trailer
- Step Products Group (SM) Header, Detail and Trailer
- Pharmacy Chain (PC) Header, Detail and Trailer
- Pharmacy Network (PN) Header, Detail and Trailer
- General Message Header, Detail and Trailer
- Message Header, Detail and Trailer

Sunsetted Files:

- Copay Header
- Copay Information Detail – Summary Level (SL)
- Copay Information Detail -Drug-Specific (DS)
- Copay Trailer
- Coverage Information Header
- Coverage Information Detail – Coverage Text Message (TM)
- Coverage Information Detail – Product Coverage Exclusion (DE), Prior Authorization (PA), Specialty (SD), Step Therapy (ST)
- Coverage Information Detail – Step Medications (SM) Triggers
- Coverage Information Detail – Step Medications (SG) Groups
- Coverage Information Detail – Quantity Limits (QL)
- Coverage Information Detail – Age Limits (AL)
- Coverage Information Detail – Gender Limits (GL)
- Coverage Information Detail – Resource Link – Drug Specific (RD)
- Coverage Information Detail – Electronic Prior Authorization Processor Detail (PR)
- Coverage Information Trailer

Coverage Information File Cross Reference:

Previous File Name	New File Name
Copay Information Detail – Summary Level (SL)	Copay Summary Detail (CS)
Copay Information Detail – Drug-Specific (DS)	Copay Product Specific Detail (PS)

Coverage Information Detail – Coverage Text Message	General Message Message
Coverage Information Detail – Product Coverage Exclusion (DE)	Product Exclusion (PE)
Coverage Information Prior Authorization (PA)	Prior Authorization (PA)
Coverage Information Specialty (SD)	Specialty Products (SP)
Coverage Information Step Therapy (ST)	Step Therapy (ST)
Coverage Information Detail – Step Medication Trigger (SM)	Step Therapy Detail (ST)
Coverage Information Detail – Step Medication Group (SG)	Step Products Group (SM)
Coverage Information Detail – Quantity Limits	Quantity Limits (QL)
Coverage Information Detail – Age Limits	Age Limits (AL)
Coverage Information Detail – Gender Limits	Gender Limits (GL)
Coverage Information Detail – Resource Link – Drug Specific	Message
Coverage Information Detail – Electronic Prior Authorization Process Detail	Prior Authorization (PA)

Consistent use changes and global Implementation Guide Changes:

- The document was updated for a consistent use of the words “list” and “file”.
- The document was updated for a consistent use of the words “medication”, “drug” and “product”.
- Removed code value restrictions from all Product/Service ID Qualifier fields.
- Updated layouts to include Field Numbers and Tags when not present as well as updated correct field names.
- Updated conditional requirements to be “required when” instead of “if”.
- Updated Figures: 1, 2, 3, 4, 5, 7, 8, 9, 10
- Updated conditional usages to be the same throughout the files.

Additional Implementation Guide Changes:

- Added Table of Figures
- Added Product Identifiers Standard Implementation Guide and Formulary and Benefit Implementation Recommendations Document to Section: Document Scope
- Updated Section: Responsibilities Of The Receiver (Technology Vendor)
- Updated Section: Formulary Status
- Updated Section: Alternatives
- Updated Section: Coverage Information
- Updated Section: Copay Information
- Updated Section: Cross-Reference Information
- Added Section: Pharmacy Network
- Updated Section: File Processing Guidance
- Updated Section: Flow One: Presenting Formulary Status
- Updated Section: Flow Two: Presenting Product Copay
- Updated Section: Flow Three: Presenting Alternatives
- Added Section: Flow Four: Presenting Pharmacy Network Status
- Updated Section: File Processing Options
- Updated Section: Full Replace Process
- Updated Section: File Header/Trailer Definition

- Moved Section: Cross Reference up in the document cause remaining section to be renumbered. In addition, the layouts were modified.
- Updated Section: Formulary Status File. File layouts were modified.
- Updated Section: Alternatives File. File layouts were modified.
- Added Section: Benefit Copay Files
- Added Section: Benefit Coverage Files
- Added Section: Pharmacy Network Status Files
- Added Section: Messaging Files
- Updated Section: Separator Characters
- Updated Section: Transmission Examples. Added new examples Pharmacy Networks.
- Updated Section: Updates and Corrections to Standards

VERSION 51, JULY 2017

Modified Copyright Statement

Modified Section: Update Process

Increased the Product/Service ID (407-D7), Product/Service ID – Source (926-HY), Product/Service ID – Alternative (958-HU), Product/Service ID-Step Drug (960-HW) from 19 to 40

Modified situation for use RxNorm Qualifier (970-JH)

Harmonized the Gender Code (721-MD) and Conditional Gender Code (C08-4T) with the NCPDP SCRIPT Standard

Modified Conditional Gender Code (C08-4T) values to M for male and F for female

Updated Drug Reference Qualifier – Alternative (918-B9) to Product Reference Qualifier – Alternative

Updated Minimum Copay (945-GS) and Maximum Copay (939-GK) to allow for a percent copay

Added new field for Copay Range Type (D64-RP) with values for Dollar and Percent

Removed ECL constraints for Gender Code (721-MD)

Modified Example Copay - Combination Terms to include new Copay Range Type (D64-RP)

VERSION 52, JANUARY 2019

The following new fields were added:

- Alternative Products Links File ID (D95-R1)
- Alternative Products Links ID (D96-R2)
- Alternative Product Groups File ID (D97-R3)
- Approximate Minimum Total Cost (D93-RV)
- Approximate Maximum Total Cost (D92-RU)
- Formulary Status Override (D98-R4)
- Quantity Related To Total Cost (D94-R0)
- Reason For Use Code (D99-R5)
- Reason For Use Code Qualifier (E01-R6)
- Reason For Use Code Description (E02-R7)
- Step Therapy Products Links ID (E03-R8)
- Step Therapy Product Links File ID (E04-R9)
- Step Therapy Product Groups File ID (E05-S0)

The following elements were renamed:

Field	Old Name	New Name
901-BP	Alternatives ID	Alternative Products Trigger ID
B62-1M	Alternatives Group ID	Alternative Product Groups ID

B66-3N	Maximum Products Per Step Group	Maximum Products Per Step Therapy Group
B65-3M	Minimum Products Per Step Group	Minimum Products Per Step Therapy Group
950-GX	Non-Listed Supplies Formulary Status	Non-Listed Medical Supplies Formulary Status
921-CU	Product Reference Number–Step Product	Product Reference Number–Step Therapy Product
922-CV	Product Reference Qualifier–Step Product	Product Reference Qualifier–Step Therapy Product
960-HW	Product/Service ID-Step Drug	Product/Service ID-Step Therapy Product
961-HX	Product/Service ID Qualifier-Step Product	Product/Service ID Qualifier-Step Therapy Product
974-JN	Step Order	Step Therapy Order
C45-9R	Step Therapy ID	Step Therapy Products File ID
C44-9Q	Step Product Group ID	Step Therapy Product Groups ID

New data files added:

- Alternative Products Links Header, Detail and Trailer
- Step Therapy Products Links Header, Detail and Trailer

The following data elements field lengths were increased:

Field	Description	Current Field Format	New Field Format
C04-1B	Benefit Stage Range End	R(10)	R(13)
C06-4R	Benefit Stage Range Start	R(10)	R(13)
925-ES	Flat Copay Amount	R(10)	R(13)
933-GB	Maximum Amount	R(10)	R(13)
939-GK	Maximum Copay	R(10)	R(13)
945-GS	Minimum Copay	R(10)	R(13)
952-GZ	Out Of Pocket Range Start	R(10)	R(13)
953-HP	Out Of Pocket Range End	R(10)	R(13)

Data Files renamed:

Record Type	Old Name	New Name
ADT	Alternatives Triggers	Alternative Products Triggers Detail
AGH	Alternatives Group Header	Alternative Product Groups Header Detail
AGP	Alternatives Group Detail	Alternative Product Groups Detail
AGT	Alternatives Group Trailer	Alternative Product Groups Trailer
AHD	Alternatives Header	Alternative Products Triggers Header
ATR	Alternatives Trailer	Alternative Products Triggers Trailer
SMD	Step Products Group Detail	Step Therapy Product Groups Detail
SMH	Step Products Group Header	Step Therapy Product Groups Header
SMT	Step Products Group Trailer	Step Therapy Product Groups Trailer
STD	Step Therapy Detail	Step Therapy Products Detail
STH	Step Therapy Header	Step Therapy Products Header
STT	Step Therapy Trailer	Step Therapy Products Trailer

New External Code List Values Added:

- Formulary Status (927-FP)
 - “B” - Brand Preferred - Indicates the payer prefers the brand over the generic.
- Record Type (601-04)
 - “APD” – Alternative Products Links Detail
 - “APH” – Alternative Products Links Header
 - “APT” – Alternative Products Links Trailer
 - “PLD” – Step Therapy Products Links Detail
 - “PLH” – Step Therapy Products Links Header
 - “PLT” – Step Therapy Products Links Trailer

The following figures were replaced:

- Figure 2
- Figure 5
- Figure 10

Global clean-up for consistence:

- Vender to technology vendor
- Drug to product or drug/product with a few exceptions such as drug compendia
- General cleanup of section names for consistency

The following sections were update:

- Formulary Status to add guidance for new Formulary Status (927-FP) for brand preferred over generic and additional cleanup.
- Alternatives to add guidance for the new elements of Formulary Status Override (D98-R4) and the new reason for use of data elements.
- Coverage Information to add clarifying language quantity, age and gender limits
- Copay Information for the new fields for an approximate total cost range
- Cross-Reference Information examples
- File Processing Guidelines for alternatives
- Transmission Level from the Sender to the Receiver to update chart
- Cross Reference Detail to include new data elements
- Formulary Status Detail
- Alternative Products File for new guidance on Formulary Status Override (D98-R4) and reason for use elements
- Alternative Products Triggers Detail for new data elements
- Alternative Product Groups Header for new data elements
- Alternatives Product Group Detail for new data elements
- Copy Summary Detail to remove value limitations on Formulary Status
- Copay Product Specific Detail for new data elements
- Step Therapy Products File (ST) and Step Products (SM) File
- Step Therapy Products Detail for new data elements
- Step Therapy Product Groups Detail for new data elements
- Transmission Examples for new data elements and deletion of Step Therapy example

New sections added:

- Alternative Products Links Files
- Alternative Products Links Header
- Alternative Products Links Detail
- Alternative Products Links Trailer
- Step Therapy Products Links Files
- Step Therapy Products Links Header
- Step Therapy Products Links Detail
- Step Therapy Products Links Trailer

VERSION 53, JANUARY 2020

New Data Elements:

- Look Back Period (F10-YH)

- Quantity Unit of Measure Code (E91-ZI)
- Quantity Unit of Measure Code Qualifier (E92-ZD)
- Reason For Use Action (E90-ZN)

New or Updated Sections:

- Coverage Information
- File Processing Guidance
- Flow Three: Presenting Alternatives
- Transmission Level From The Sender To The Receiver
- Cross Reference Detail
- Formulary Status Header
- Formulary Status Detail
- Alternative Products File
- Alternative Products Trigger Detail
- Copay Product Specific Detail
- Age Limit Detail
- Gender Limits Detail
- Quantity Limits Detail
- Prior Authorization Detail
- Specialty Products Detail
- Step Therapy Products File (ST) and Step Therapy Products Group (SM) File
- Step Therapy Products Detail
- General Message Header
- Message Header
- Separator Characters

- Updated Transmission Examples:
 - Formulary Status
 - Alternatives
 - Formulary Information Based on Indication
 - Copay – Summary Level and Copy Product Specific
 - Coverage Restrictions
 - Messaging
 - Pharmacy Networks
 - Error Scenario – Formulary Status
 - Error Scenario – Age Limits
 - Section: Formulary Information Based on Indication

Deleted Sections:

- Alternative Product Links (AP)
- Step Therapy Products Links File (PL)

Figures Update:

- Figure 2: Formulary and Benefit Summary Information Model
- Figure 5: Flow Three: Presenting Alternatives
- Figure 10: Transaction Level from Sender to Receiver

General grammatical and typographical errors