Proposed changes to resource definitions for DaVinci PDEX Drug Formulary

Eric Ellsworth, 2021-07-22

This proposed model is based on EE's prior work evaluating formularies to help consumers investigate them, and was refined during the CMS FHIR Connectathon Jan 7-9, 2020, and finally finished in the CMS FHIR Connectathon Jul 20-22 2021.

Background

Formularies are Member Contract Documents

As it exists in its full form, a formulary is a component of insurance policy that essentially functions as a contract addendum stipulating terms around coverage of drugs. Formulary documents contain a number of kinds of information:

- Explanatory text about how tiers, drug lists, and other terms of drug coverage work
- Defines non-coverage of entire classes of drugs (e.g. hair loss, erectile dysfunction etc.) in textual form
- Provides contextual information about the scenarios in which drugs may or may not be covered often called the "clinical indication"
- Defines specific requirements around drugs that require prior authorization and/or step therapy.
- Defines tiers of drugs
- Lists drugs and their associated tier, usually specifying drugs in very broad ways (drug name, use of capitalization to specify

Formularies themselves typically **do not** specify cost-sharing amounts for drug tiers; cost-sharing is established at the plan level for each plan referencing the formulary.

In creating this proposal, I reviewed several formulary documents published online:

- UPMC Advantage Choice (Dec 2019)
- Kaiser Permanent Colorado Commercial Formulary
- Kaiser Permanente Colorado Specialty Tier Drug List
- Kaiser Permanente FEHB Formulary
- Bright Health Colorado Formulary

I've also read a large number of other formularies; this proposal reflects general knowledge derived from that.

Most payers maintain a limited number of formularies, often one per market segment. Within employer plans (ERISA-regulated) there may be some customization of formularies for specific employers (e.g. self-insured entities where the insurer and the PBM function as Administrative Service Organizations) – for these plans the formulary itself may be specific to one or a small number of plans. A plan usually explicitly references one formulary, but by dint of the full member contract and associated contract documents, other lists of drugs and coverage may be implicitly referenced. For example, most payors

do not publish consumer-facing lists of physician-administered drugs such as those delivered intravenously or within other parts of the body; such coverage lists are managed separately.

As stated above, formulary documents define tiers of drugs. These tiers are defined numerically and are "semi-ordinal" –a higher number roughly indicates a more costly drug, but there are cases that break the ordinality (e.g. physician-administered/medical service drugs, "wellness drugs", etc). The formulary itself does not define specific cost-sharing for those tiers; that cost sharing is defined within the prescription drug coverage in a plan (whether medical or standalone drug plan) making reference to the tiers defined in the formulary. Formulary documents also serve other purposes: they make general statements of policy by the carrier regarding prescription drugs, they state specific drugs, drug classes, or utilization scenarios that are not covered. A formulary document's list of covered drugs is frequently grouped by drug class and/or clinical utilization scenario for faster use by physicians.

Within a "legacy" (print) formulary, drugs in the drug list are presented as a drug name alone, with no associated dose form or strength. Since formulary documents have historically been geared toward providers, listing a drug without any dose or strength likely indicates coverage for all commonly prescribed dose forms (e.g. tablets/capsules for many oral medications, injections for insulin and other drugs, topical creams for external conditions, etc.). Coverage of uncommon forms (e.g. injectable Lipitor) is left unstated, meaning possibly that the issue would be dealt with either in via prior authorization or exception request or within the claims adjudication process.

Problems Defining Formularies in Machine Readable Form

Machine-readable formularies are often defined with RxCUI codes to avoid having to declare drugs at the level of an individual manufactured product (i.e. NDC codes). Some formulary data collection schemes (e.g. Medicare Part D formularies) use a defined mapping between NDC and RxCUI to allow insurers to reference other data that may use NDC codes or readily be crosswalked to NDC codes. Within the ACA markets, formularies are collected from issuers using SERFF templates (SERFF Prescription Drug template). These templates are Excel spreadsheets which are filled in manually by personnel focused on regulatory approval. The SERFF templates currently use only RxCUI codes that specify strength of brand and generic drugs (i.e. TTYs specified in the RxTerms subset of RxNorm, which are all drug-strength-dose-form specific), and make no statements about broader coverage (e.g. coverage of all strengths within a dose form or if there are exception processes for infrequently used dose forms). This leaves uncertainty about whether relevant dose forms were intentionally (i.e. not covered) or unintentionally (i.e. actually covered) left out of the list. Such unintentional blanks can occur because the time lag between the time that a pharmaceutical manufacturer changes dose strengths and the time that something prompts the insurer or PBM to closely review the list of covered drugs.

In assessing the accuracy of formulary data, it is also important to take into account is the way that coverage of drugs is established. Within the insurer (or within the associated PBM), there is a Pharmacy and Therapeutics Committee (aka "tech committee") that assesses the drug for its cost-benefit and safety profile, as well as any legal issues concerning whether or not to offer coverage. This committee makes a determination of whether to cover the drug, and other actors in the insurer/PBM undertake contracting to define the price paid for the drug; those two elements determine whether the drug is on-formulary and what tier it is on.

In most cases the price that the insurer or PBM pays for the drug **does not** vary by drug strength, and thus most strengths of the same dose form (e.g. 10, 20, 40, 80 mg of an oral pill) are covered in the same way, mean all such strengths are on the same tier. However, coverage for different dose forms is **not** generally the same, as the price to the insurer/PBM will be quite different for an injectable form of a drug than an oral pill, and the "uncommon" dose form is generally only dispensed as a fallback when the "common" dose form will not work for a specific patient. Therefore the tech committee may not generally specify coverage at the level of drug/dose form/strength combination that is the required granularity for the RxCUIs used in machine-readable formularies.

Another problem arises when a pharmaceutical company decides to change the available dose forms (e.g. split a minimum 10 mg dose into 5 mg and 15 mg). When this happens, the FDA removes the NDC code of the old dose forms from the list of NDCs that it publishes daily. RxNorm then uses this change to the NDC list to mark the drug as "archived". However, unless the reason the FDA "unlisted" drug is a recall scenario (safety issues), the drug remains available at the pharmacy until supplies run out. The "archived" drug list overwhelmingly composed of drugs that really aren't available, so it's very hard for a non-expert person at an insurer to figure out when an archived RxCUI should or should not be included in the machine-readable drug list. Similarly, if a new dose form is added, but the insurer has not looked closely at these changes (which do not merit new attention from the tech committee) it is quite likely that the new dose form is also not listed in the machine-readable data.

Further compounding the problem in the ACA markets is the fact that data is entered into the SERFF Prescription Drug template manually. This template is submitted to the state insurance department as part of the insurer's process of getting approval to offer its plans and rates in that state for that year. As such the person entering the data is not only non-expert, their role is mostly administrative, with goals/accountability around state and/or CMS approval for their plans rather than accurate information for consumers (this is a problem with all the SERFF data used for Healthcare.gov). In practice this means that someone with limited knowledge of the clinical or price reasons of coverage is obliged to pick a detailed set of RxCUIs to include in the machine-readable formulary with little to no understanding of the "true" coverage parameters. This approach is subject to introduction of many errors of omission.

Yet another problem concerns the scope of formulary itself. Consumer-facing formularies typically only specify coverage of drugs that consumers can buy and take themselves; drugs administered by physicians or at a hospital are not listed. Some insurers also define a separate formulary for specialty drugs (many of which fall on the line between physician-administered and patient administered), while other insurers list specialty drugs within the same formulary as other consumer facing drugs. As mentioned above, nearly all insurers exclude certain classes of drugs (cosmetic, ED, vitamins) from coverage. Some drugs may be covered under certain circumstances, such as Botox for overactive bladder but not for facial appearance or vitamins for prenatal care or medical needs but not general wellness.

Many machine-readable formularies and instructions for completing them lack clear guidance on the scope of drugs to include, not only in terms of the drugs themselves but dose forms and strengths that should or should not be included.

A clear indication of scope will dramatically reduce the likelihood of mistaken conclusions of non-coverage, as explained further below.

Consequences of Using Missing Rows to Indicate Non-Coverage

In most schemes involving machine-readable formularies, non-coverage is indicated by non-inclusion of a particular code- there is no positive statement of non-coverage. This is also the case in "legacy" formularies – drugs that are not explicitly listed are presumed not be covered. However, in standard practice "legacy" formularies are embedded in a set of contextual knowledge and investigative practices that precede a black and white response of non-coverage in the form that the FHIR Formulary API will deliver.

Formularies that report at a less granular detail (atorvastatin is covered but Lipitor is not) can avoid many false conclusions like "liquid atorvastatin is not covered" when in fact common practice is simply to list the commonly used form of atorvastatin (as a pill or capsule) and the payor would pay for liquid atorvastatin.

With machine-readable formularies, however, APIs are set to render a yes/no answer on coverage. Furthermore, applications which consume this result have little way of establishing the context or veracity of the result, but must pass on the result verbatim. For example, a plan shopping tool that uses coverage of a drug to rank plans or calculate expected out-of-pocket costs would mistakenly calculate very high costs for that plan.

Without clear delineation of the scope of RxCUIs included in the formulary, it is very easy to build a search universe of RxCUI codes that were excluded from the formulary not because of non-coverage but because of different assumptions about the scope of drugs to be included.

For example, consider the case where one insurer chooses to include birth control medications in the machine-readable formulary while another insurer does not. The application developer is unaware of this, and simply chooses to allow searching for all RxCUIs they assume should be covered (the most likely scenario in reality). For the insurer that decided not to list birth control medications, the results will incorrectly show that they do not cover any birth control when in fact they do, they just didn't think they were in scope for the formulary list.

A robust resource implementation could offset many of these problems by clearly defining the scope of drugs that the formulary intends to cover.

An additional problem is if one insurer decides to use a different RxCUI code than another to indicate coverage for a particular drug, say if one carrier puts in Lipitor 10 mg, 40 mg, and 80 mg while another puts in 10 mg, 20 mg, 80 mg. In this case a user will always get the wrong answer for both 40mg and 20mg – one carrier covers it while another doesn't.

A better way to deal with this is to move up one level of granularity to the SXDG RxCUI (Lipitor Oral Pill), and allow exceptions to be named specifically. So the insurer could say we cover all strengths of Lipitor Oral Pill except 40mg. This would address cases such as with Nexium, where one strength is on-patent and the rest are off-patent/generic. Using SXDG_Rxcui with carve-outs would dramatically reduce both the number and complexity of RxCUI codes to be entered. This level of granularity is also much closer to the average consumer's intended shopping scenario. After all if the 40mg is really not covered they can just adjust their script to take 2 x 20mg.

Proposed changes for FHIR Formulary Resource

This proposal suggests some (hopefully) uncomplicated ways the FHIR formulary resources can be adjusted to provide results that are much more robust to the problems demonstrated above. It would allow consumers and application developers to have more confidence in the results given by FHIR formulary resources without requiring that the underlying data be in perfect condition, or that the API consumer have perfect understanding of the intended scope of the machine-readable formulary asserted through the API.

Goals of this proposal

- Ensure that the formulary lookup functionality within FHIR meets consumer needs and is structured to minimize complexity of data and of required inputs.
- Make the resource and associated drug lookup/shopping functionality less likely to have incorrect data by changing the granularity/cardinality of drug codes from strength specific RxCUIs to higher level RxCUIs (e.g. SXDG TTY) and allowing specific carve-outs.
- Reduce the likelihood of returning incorrect results by creating a definition of the scope of drugs addressed or not addressed by the current formulary.
- Simplify the generation and management of formularies by creating a separate Formulary resource that defines tiers but not plan-specific cost-sharing
- Add elements to the Formulary resources that address the scope of the other drug list and other key contractual terms specified by current “legacy” formularies.

Significant changes:

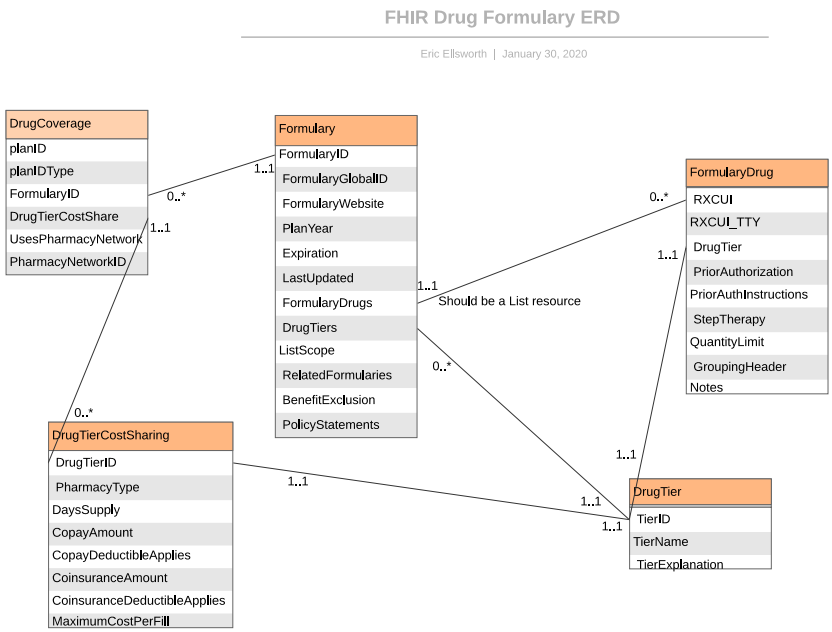
- Proposes established a separate Formulary resource which defines tiers and a drug list but does not include details of cost sharing, consistent with typical definition of formularies
- Add elements to Formulary that incorporate policy related statements found in PDF formularies.
- Revise the CoveragePlan (suggest calling DrugCoveragePlan) to reference the Formulary resource
- Separate the TierDefinition resource into two distinct resources: a DrugTier resource that is associated with a Formulary resource, and DrugTierCostSharing resource that is associated with the DrugCoverage resource.
- Enable use of RxCUI TTYs that do not specify strength or dose form

Additional Use Case Language:

- A payor wishes to create and expose a Formulary document in machine-readable form that can be rendered into human-readable form with the additional of only explanatory language (i.e., the FHIR resource contains relevant policy language)

Entity Resource Diagram

https://www.lucidchart.com/documents/edit/5e88d96b-ea49-40fd-9360-cacab26278f7/0_0



Updated Definitions of Resources

DrugCoverage resource			
Element	**Type**	**Description**	**Notes**
planID	Character 1..1	Identifier of the plan	This may need to reference another Plan or Coverage resource, as drug coverage is often included within a medical plan.
planIDType	Character 1..1	Identifies the type of plan (drug or medical)	Determines which reference to use. If not needed can delete.
FormularyID	Character 1..1	Identifier of the formulary used by this plan	
DrugTierCostSharing	Collection of DrugTierCostShare	Contains the cost-sharing requirements for all of the tiers defined in the	

		Formulary resource used by this plan	
UsesPharmacyNetwork	Boolean	Indicates whether the plan requires a consumer to use in-network pharmacies to obtain the contract price and cost-sharing	
PharmacyNetworkID	Character	networkID of the pharmacies a consumer can use	Probably contained within an existing Network resource

Formulary resource			
Element	**Type**	**Description**	**Notes**
FormularyID	character 1..1	Formulary identifier used by plans	This may identifier may be local unique but not globally unique; submissions made in SERFF currently use locally but not globally unique identifiers for formularies
FormularyGlobalID	character 1..1	Global formulary identifier enabling a consumer to reach their own plan's formulary and correctly identify this formulary	A global unique identifier that can be displayed to consumers and providers for searching online formularies. This global identifier should also enable a consumer or designated app to reach the URI for this specific formulary
FormularyWebsite	url 0..1	URL for a website associated with the formulary	Some carriers may have a website with resources for consumers regarding their formulary, including prices of specific drugs (not just copay or coinsurance), related drugs, etc.

PlanYear	character 1..1	The plan year for which this formulary applies	Formularies are associated with a particular plan year. This is a descriptor and could replaced by startDate
Expiration	character 1..1	Expiration data of the formulary	Date this formulary document goes out of validity (typically same as expirationDate of associated plans)
LastUpdated	datetime 1..1	Date the formulary was last updated	Formularies are often updated a few times during a given plan year
FormularyDrugs	List 1..1	The List resource containing the specific drugs and tiers on this formulary	Note that the list is a distinct resource (similar to the distinct Formulary and Drug List sheets in the SERFF Prescription Drug template)
DrugTiers	Collection of Tier resources	Definition of the tiers for this formulary	Does not include cost sharing values, as these can vary among different plans that use the same Formulary
ListScope	Collection of character	Defines the types of drugs contained by the FormularyDrugs List resource	Some payers use different formularies for different types of drugs (e.g. specialty drugs, medical service drugs, vitamins), while others use a single formulary for all drugs. Additionally, some drugs may be paid for through medical rather than drug benefits.
RelatedFormularies	Collection of character	Identifiers for related formularies	E.g. the payer uses a separate specialty formulary, this would contain the reference for that formulary
BenefitExclusions	Collection of character	Statements that specify specific exclude classes of	E.g. hair loss, erectile dysfunction drugs, etc.

OtherPolicyStatements	Collection of character	Other statements of policy	E.g. if a consumer chooses a branded drug when a retail drug is available s/he is responsible for the branded drug copay plus the difference in underlying cost of the drug.

FormularyDrug resource			
Element	**Type**	**Description**	**Notes**
RXCUI	Character	RXCUI code identifying the drug or drug group	Should be able to include TTY: SBD, SCD, SBDG, SCDG
RXCUI_TTY	Character	RXCUI type code identifying the type specified	TTYs of SBDG, SCDG will need to be deferenced into the correct SBD and SCD drugs
DrugTierID	DrugTier	DrugTier resource for this drug	
PriorAuthorization	Boolean	Whether prior authorization is required	Might consider integer if there are multiple codeable categories of prior authorization to be returned
PriorAuthInstructions	Character	Relevant instructions for prior authorization	
StepTherapy	Boolean	Whether step therapy is required	Might consider integer if there are multiple codeable categories of step therapy to be returned
QuantityLimit	Character	Limits on quantity over particular period of time	

GroupingHeader	Character	Header or category under which this drug falls for reference	Permits listing of drugs by category, also permits any category specific information to be presented
Notes	Character	Notes on this specific drug such as dose form coverage or non-coverage	

DrugTier resource			
Element	**Type**	**Description**	**Notes**
DrugTierID	Character	Identifier for the drug tier	Usually this is an integer, but since drug tiers are not ordinal and might have modifiers, it may be better to permit characters
TierName	Character	Visible name for the drug tier	This is as would be visible to a consumer or provider on a printed/rendered formulary
TierExplanation	Character	Explanations of drug tiers and specific requirements	

DrugTierCostShare resource			
Element	**Type**	**Description**	**Notes**
DrugTierID	Character	Identifier for the drug tier	
PharmacyType	Character	Whether this drug is available at a retail, mail order or specialty pharmacy	
DaysSupply	Character	Number of days supplied under this cost sharing	E.g. 30 day or 90 day
CopayAmount	Money	Amount of Copay	
CopayDeductibleApplies	Boolean	Whether the plan's relevant (medical or drug) deductible applies	Could also be character if additional

			information is needed
CoinsuranceAmount	Percentage	Percentage of the drug's cost the consumer is required to pay	Note that in some cases payors list the amount THEY will pay. This is confusing and the standard should require the use of consumer's payment
CoinsuranceDeductibleApplies	Boolean	Whether the plan's relevant (medical or drug) deductible applies	Could also be character if additional information is needed
MaximumCostPerFill	Money	Monetary limit on the cost of the fill	E.g. for this kind of benefit (40% coinsurance after deductible up to a maximum of $250)