Study of Drug Coverage System in Formulary

By

Ayush Kumar Tiwari

Dissertation submitted for the partial fulfillment of the

MBA Pharmaceutical Management

Academic year, 2017-2019

The IIHMR University, Jaipur

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INSTITUTE OF HEALTH
MANAGEMENT RESEARCH
(WHO Collaborating Centre for District Health System Based on Primary Health Care)

IIHMR UNIVERSITY

TO WHOM SO EVER MAY CONCERN

This is to certify that **Mr. Ayush Kumar Tiwari**, student of MBA Pharmaceutical Management from The IIHMR University, Jaipur has undergone internship training at **Decision recources group, Gurugram** from 4th February to 4th May 2019.

The Candidate has successfully carried out the study designated to him during internship training and his approach to the study has been sincere, scientific and analytical.
The Internship is in fulfillment of the course requirements.

I wish him all success in all his future endeavors.

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DRG
DECISION RESOURCES GROUP

Date: 27th May 2019

The certificate is awarded to

AYUSH KUMAR TIWARI

In recognition of having successfully completed his
Internship in the department of

MACC DATA, FINGERTIP FORMULARY

and has successfully completed his Project on

DRUGS COVERAGE SYSTEM IN FORMULARY

DECISION RESOURCES GROUP, GURUGRAM, HARYANA

He comes across as a committed, sincere & diligent person who has a strong drive and zeal for learning

We wish him all the best for future endeavors

Shanbhag

Director, MACC DATA

(VIKRAM SHANBHAG)

Head-Human Resources

Kaushal

THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled Study of **Drug Coverage System in Formulary** and submitted by **Ayush kumar Tiwari** Enrollment No. **118** under the supervision of **Dr. Sandeep Narula** for award of MBA in Pharmaceutical Management in the University carried out during the period from 4th February 2019 to 4th May 2019 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Signature Ayush

Ayush Kumar Tiwari

Acknowledgement

Without a proper combination of inspection and perspiration, it's not easy to achieve anything. There is always a sense of gratitude, which we express to others for the help and the needy services they rendered during the different phases of our lives. I have taken efforts in this project. However, it would not have been possible without the kind support and help of many individuals and organizations. I would like to extend my sincere thanks to all of them.

I am highly indebted to **Mr. Vikram Shanbhag**, Director, MACC Data Team, Decision Resources Group, Gurugram for his guidance and constant supervision as well as for providing necessary information regarding the project and for his support in completing the project. His perceptive criticism kept me working to make this project more genuine proof.

I would like to express my gratitude towards Research Analyst, **Mr. Aditya Verma** for their kind co-operation and encouragement which help me in completion of this project.

I would like to express my special gratitude and thanks to organization's persons for giving me such attention and time.

I would like to extend my heartfelt gratitude towards my mentor, **Mr. Sandeep Narula Dean & Associate Professor**, The IIHMR, Jaipur for his continuous support and guidance throughout this project.

My thanks and appreciations also go to my colleague in developing the project and people who have willingly helped me out with their abilities.

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TO WHOMSOEVER MAY CONCERN

This is to certify that _____, student of MBA Hospital and Health Management/ Pharmaceutical / Rural Management from The IIHMR University, Jaipur has undergone internship training at _____ from _____ to _____.

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The Internship is in fulfillment of the course requirements.

I wish him all success in all his future endeavors.

Dean, Academics and Student Affairs
The IIHMR University, Jaipur

Professor
The IIHMR University, Jaipur

The certificate is awarded to

Ayush Kumar Tiwari

In recognition of having successfully completed her

Internship in the department of

MACC DATA, Fingertip Formulary

and has successfully completed her Project on

TO STUDY THE DRUG COVERAGE SYSTEM IN FORMULARY

Date

_____

Decision resources group , Gurugram

He comes across as a committed, sincere & diligent person who has a strong drive and zeal for learning. We wish him/her all the best for future endeavors

Training & Development **Zonal Head-Human Resources**

THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

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Signature

Ayush Kumar Tiwari

Introduction ofU.S. Healthcare-

The U.S. healthvcare system is very different among advancedvindustrialized countries. The U.S.ahealthcare system does not have a uniform health system..The U.S. health care system can best be described asva hybrid Health insurance system . In 2014, 48 percent ofU.S. health care spending came from private funds, with 28 percent coming from households and 20 percent coming from private businesses. The Central government accounted for 28 percent of spending and state and local governments accounted for 17 percent. Most health care, even if publicly financed, is delivered privately.

Generally, US healthcare is covered by Public Healthcare system and Healthcare marketplaces. Public healthcare system is covered by Medicare which is generally for people older than 65 years old, Medicaid which is Federal and state funded program but administered by State only, CHIPS programs which provide insurance to those children which are not eligible for Medicaid and Military programs through TRICARE and others. Private healthcare consists private insurance companies which provides healthcare plans of different varities depends on coverage of drugs in specific plans.

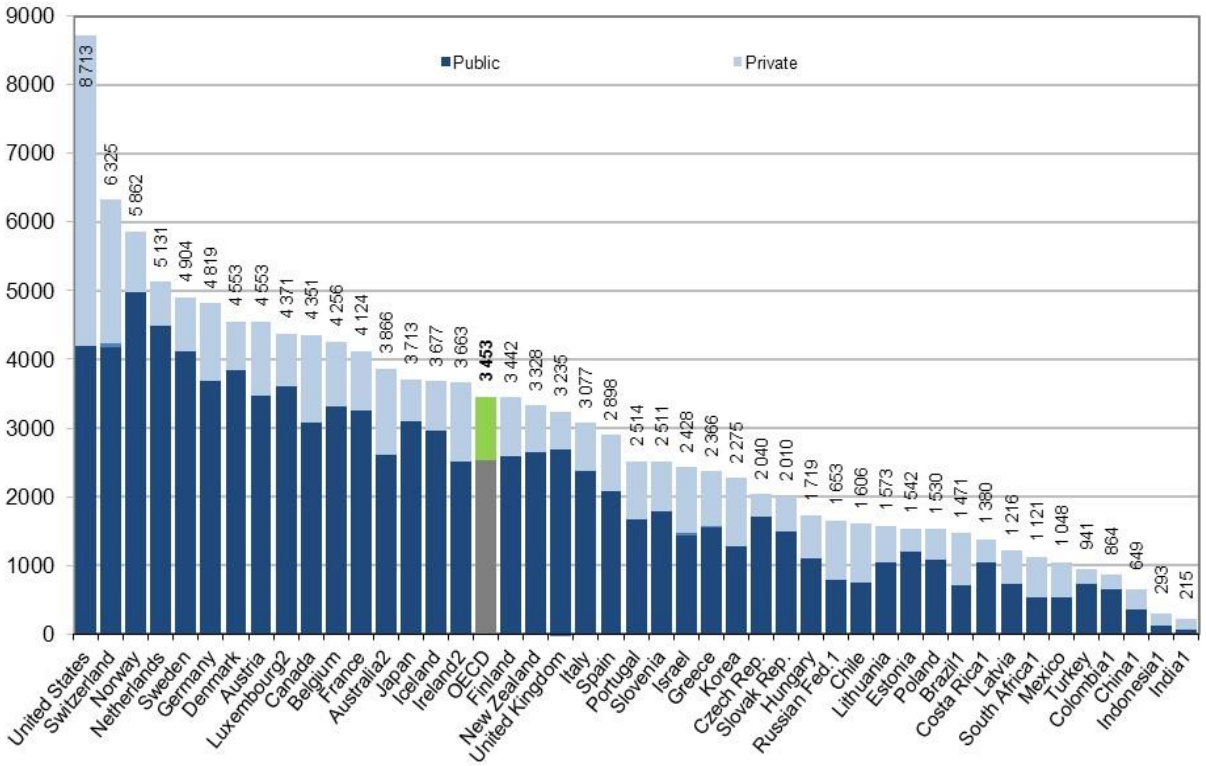
On a per capita basis, the U.S. spends more than double the $3,453 average of all OECD countries .

Every Health plan has a unique preferred drug list, which is responsible for identification of drugs which is covered under health plan. These type of drug lists are necessary because Payers want to pay for those drugs which are covered. Providers need to check these preferred drug lists each time they are going to prescribe drugs.

Formulary is also a tool which has significantly reduced the burden of medicine costs for payers because there are preference of generics over brands during prescription of drugs and other methods etc.

This is US healthcare has rising health expendiature. This is the expendiature comparison of some countries in which US is on 1st position

Health Expenditure per capita, 2013 (or nearest year)



Literature Review –

- **Impact of Formulary Restrictions on Medication Use and Costs, Xian Shen, PhD; Bruce C. Stuart, PhD; August 26, 2017**. Describes restrictions have significant effect on drug cost. As generic with less quantity limits can also have more cost for monthly use.

- **MeltemSezer and Franziska Bauer,Introduction to the U.S. Health Care System, 2017.**It describes about US healthcare system in 2017 and tells about public And private health insurance providers.What was the problem of uninsured
  People and why were they not insured. My study tells about steps taken to cover more people and overcoming the challenges of population coverage.

- **American Patients First,The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,May 2018.**

  The U.S. Department of Health & Human Services suggested four challenges in the American drug market: Higher Prices of listed drugs,Lack of negotiation tool due to which Seniors and government programs overpaying for drugs, High and rising out-of-pocket costs for consumers, Foreign governments free-riding of of American investment in innovation Under President Trump,

OBJECTIVES

1. **To Study Drug coverage system in formulary.**

Scope of study-

- **This study explains about Drug formulary.**
- **Tier system used by formularies**
- **Restrictions System used in Drug formulary.**
- **Cost- sharing System in US healthcare.**

2. **To understand Fingertip Formulary in context of Drug Coverage.**

METHODOLOGY

Research type is secondary research. Research is done with the help of Articles, Publications and Websites.

Number of days taken to complete this study is 3 months from 4th February 2019 to 4th May 2019.

Drug Formulary-

The Drug formulary is listed information of drugs prescribed by doctors, these can be Brands and generics drugs. Doctors used to identify the most valuable drug which can be given to patients.

There is a committee called P & T committee responsible for designing of drug formulary. It involves Actively practicing doctors and pharmacists.

The formulary usually changes monthly or quarterly. It may be different also.

Maximum Drug formularies come with Tiered formuaries. It can be –

- 2 Tier formulary
- 3 Tier formulary
- 4 Tier formulary
- 5 tier formularyetc.

The Tier of formulary is directly related with the cost. The drugs on high tiers cost higher than the drugs in lower tier.

It depends on plans that some Plans can charge a deductible for the specific tiers and not charge for other tiers.

Drugs are added or deleted on formulary/ drug list year to year or within a year. Some changes on formulary also made,when drugs become out of the market.

Drug formularies or Drug list is a gateway to get Coverage of prescription Drugs in health plans in United states. It impacts Pharmacists, Purchaser, Doctors and patients.The main objective behind formulary is to give cost-effective medication and high quality care.

Generics drugs are generally assigned to lowest tiers and Brand and speciality drugs assigned to higher tier.

Most health plans contract with a separate company to administer their prescription drug formulary, known as a pharmacy benefit manager (PBM). PBMs are responsible for negotiating drug prices with pharmaceutical manufacturers and pharmacies. PBM advocates note that these organizations aggregate purchasing power to lower drug costs for health plans and patients, and many PBMs provide strategic services to avoid medication errors and drug misuse.

Examples of **utilization management** protocols common within drug formularies include:

Coverage Restrictions – Coverage restrictions determines the protocols applied on covered drugs in formulary.

- **Prior Authorization** – Prior authorization is a method to cover drugs by taking authorization from Providers .For prior authorization of a drug, it is required to take a approval through the online portals or websites, telephone and by submitting written request of coverage.

- **Quantity Limits-** It is the restriction on Quantiy assigned for a particular drugs in the health plan. Generally, quantity assigned on monthly basis.

  Example-Tadalafil – 30 tablets per 30 days

- **Step Therapy**- Step therapy means if Generic drug or lower level of treatment does not work for a disease condition then Health plan can approve higher level of treatment or more expensive medication.
- **Mail-Order Criteria** –Mail order is related with the ordering online from pharmacy. Generally, it requires higher amount of copay.

Patients are adviced to read the terms and conditions associated with Preferred drug list and make sure to understand relationship of Copays with Tiers.

Some plans require patients to pay the full cost of their prescribed medications until they reach their deductible, and only afterwards charge patients copays according to the formulary. Plans may also use a coinsurance system where the patient pays a percentage of the drug cost, rather than a fixed dollar copay amount.

There can be two types of coverage in formulary –

Open type of Coverage- Through thesetype of plans, provider can prescribe those drugs which are not covered on formulary.But it requires a higher amount of addition copay for additional drugs.

Closed type of Coverage – These types of plans cover only those drugs which are present on preferred drug list.

Cost sharing of health plans include-

- Premiums
- Co-insurance
- Deductibles
- Co-payment

Fingertip Formulary –

Fingertip Formulary is a large database software which keeps the detail of drugs.The datails can be-

- Prior authorization of drugs
- Quantity Limits of drugs
- Step Therapy of drugs
- Speciality Status of drugs
- Tier status of drugs

If the drug is related with lesser copay then Tier will go to the lesser one.

Currently, It keeps the records of more than 2800 drugs used in United States of America.

For, client ease company has decided to upgrade it in more interactive version.

Fingertip formulary is generally known as the FF by its client in US market.

Fingertip keeps a large set of Copay research data which is needed by clients time to time.

Company has launched fingertip formulary app which can run easily on Android devices and Apple Ipone products.

Fingertip keeps records in different segmented tabs which has different purpose.

Health plan has –

- A unique plan name
- A unique plan number
- Website address of plan
- Formulary address related with plan
- Metal status of formulary
- Formulary comments applicable to the Plan .
- Province or State where plan is applicable
- Provider name etc.

These specifications help to identify the specific plan easily.

Every month different formulary drugs can be updated with-

- SP list (speciality pharmacy)
- PA list (Prior authorization)
- QL list (Quantity list)
- ST list (Step therapy)
- ACA list or O$ copay list

- NP list (Non- preferred list)etc.

- Besides these lists there are drug addition list, drug deletion list .

Formulary database keeps records of all listed data on different docs.

Clients need instant update and current situation of drugs in a formulary, so it is necessary for the company to put the current data in database as soon as possible after the release of new formulary.

To code a formulary there are some specific terms which is necessary to know-

Brand default - It means if a Branded drug is not present on formulary, the tier assigned for the brand will be brand Default Tier. It is different for different types of plans e.g. Closed plans and Open Plans.

Generic Default- It means if a generic drug is not present on formulary, the tier status assigned to the generic will be generic default. Same as brand default it is also different for different plans.

Can a single drug have Tier status with more than one restriction-

For example suppose a contraceptive drugEnpresse has Zero dollar copay , and certain quantity limit (6 per month) is assigned in formulary) Then tier will be assigned as per formulary tier means Zero with QL restriction .

Same like this suppose a drug Cialis which is used in Erectile dysfunction can have prior authorization and quantity limits and step therapy depends on plan, So it has multi restrictions with formulary tier.

So, clients have intrest in knowing restriction changes and tier changes in drug more fastly, so that they can take competitive advantage over their competitors.

Drugs can have-

- Medical benefit
- Pharmacy benefit

some others Challenges for which coding is necessary for clients are –

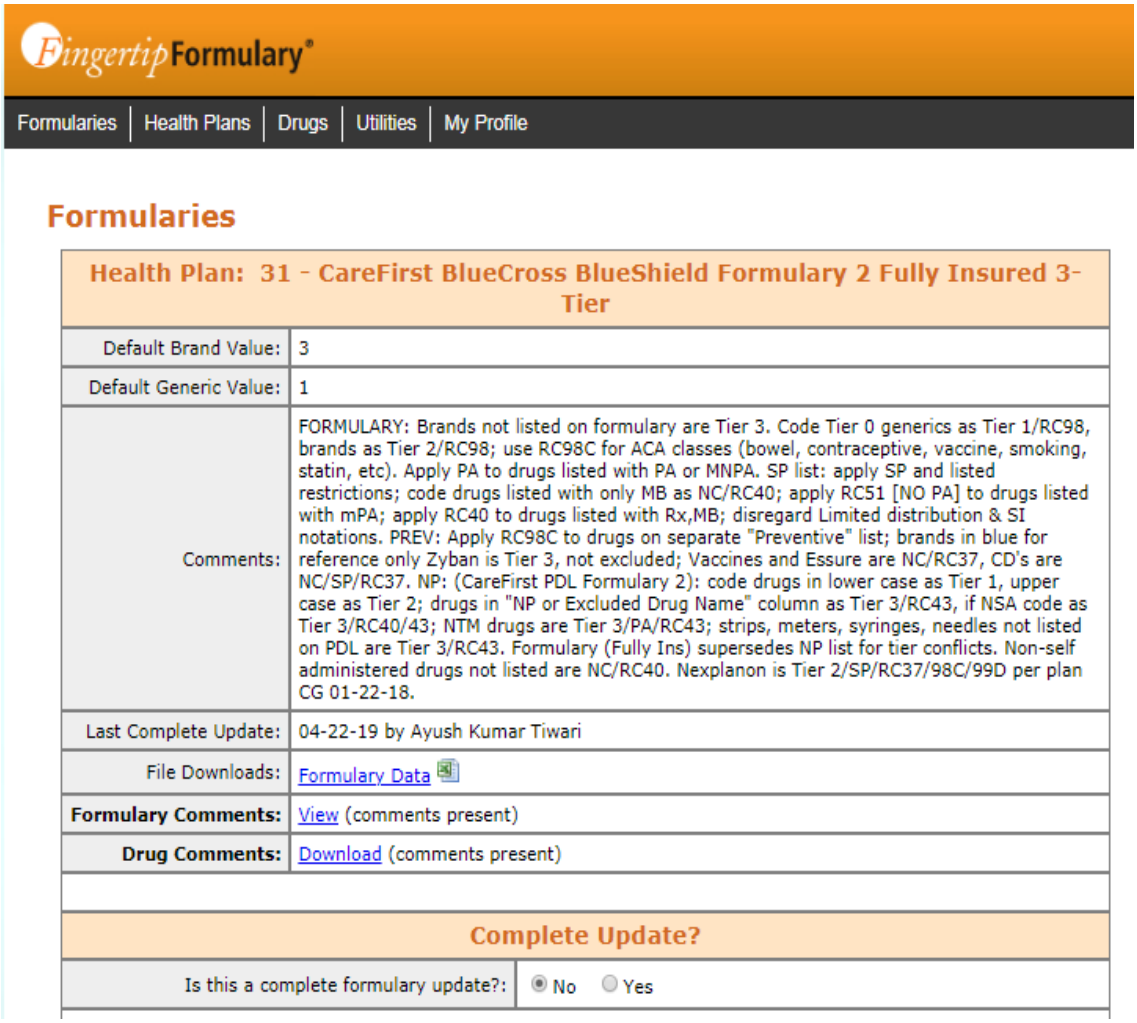
- Drugs with Age limit
- Drugs wirhGender limit
- Drugs having Prior authorization related with age
- Drugs can have different strengths with different Tier status and restrictions.
- Drugs with different dosage forms can have different Tier status and restrictions.
- Drugs with different strengths can have different tier status and restrictions.
- A single drug can be at different tier in different plans it means copay for same drug will be different for different plan. So, it is necessary for providers to understand the copay system for same drug in different plans.
- A payer is health insurance company which provide insurance to the person. A payer always wants from provider to prefer generic drugs over branded drugs unless not required. So, coding is necessary for cost reduction from the payer point of view. Because it gives updated information fastly.

Fingertip Formulary Coding Procedure –

Coding of formulary requires –

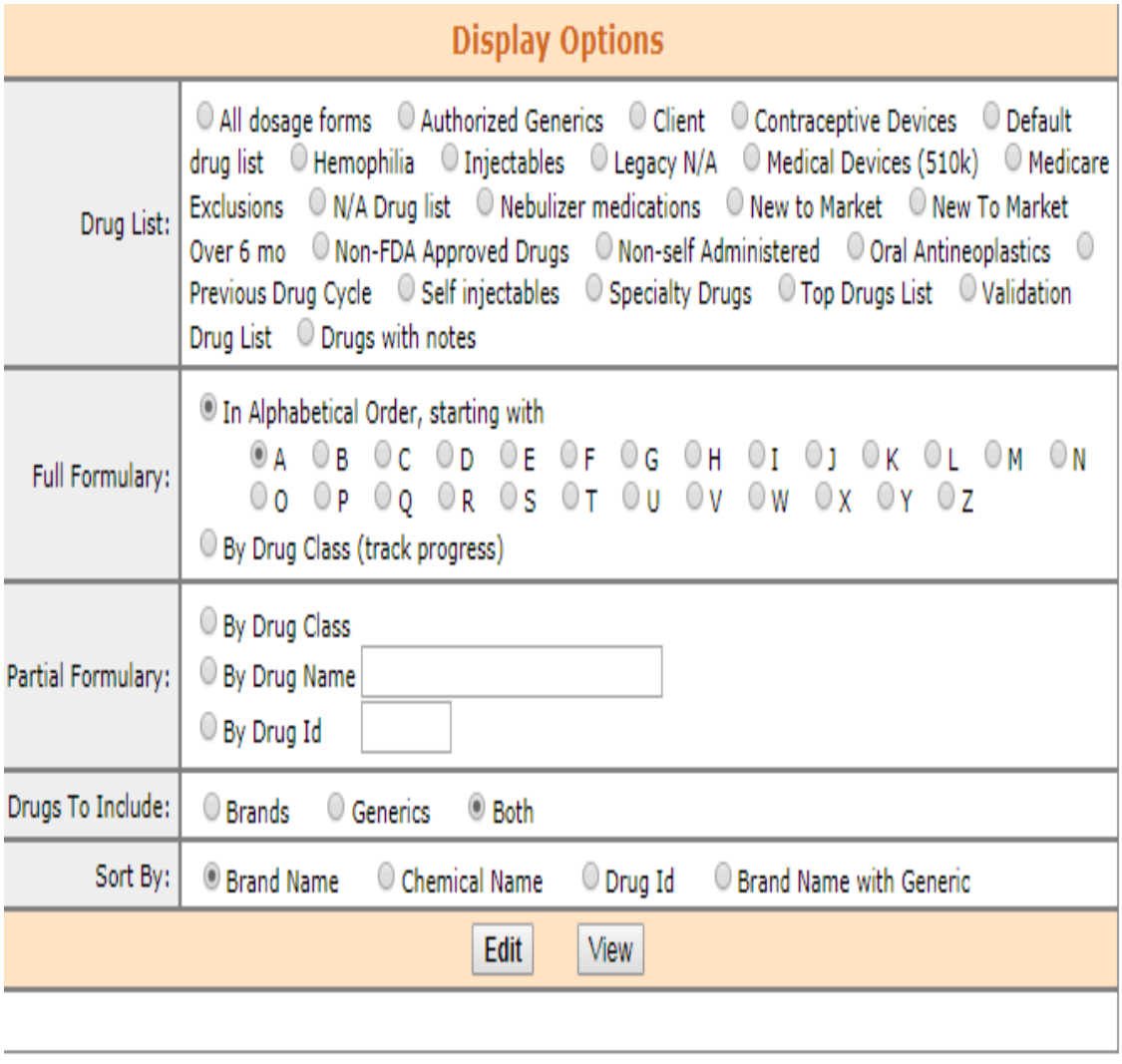
- Preferred drug list or drug formulary.
- Any other supplement list (SP list, PA list, QL list,Update doc means drug addition and drug deletion doc) etc.
- Scrape or Automatic drug extraction list.

After login Fingertip formulary a Health Plan screen appears which looks like



It contains-

- Unique health plan Name and unique no.
- Default Brand value
- Default Generic Value
- Plan Comments which helps in putting specific drug status in Fingertip.

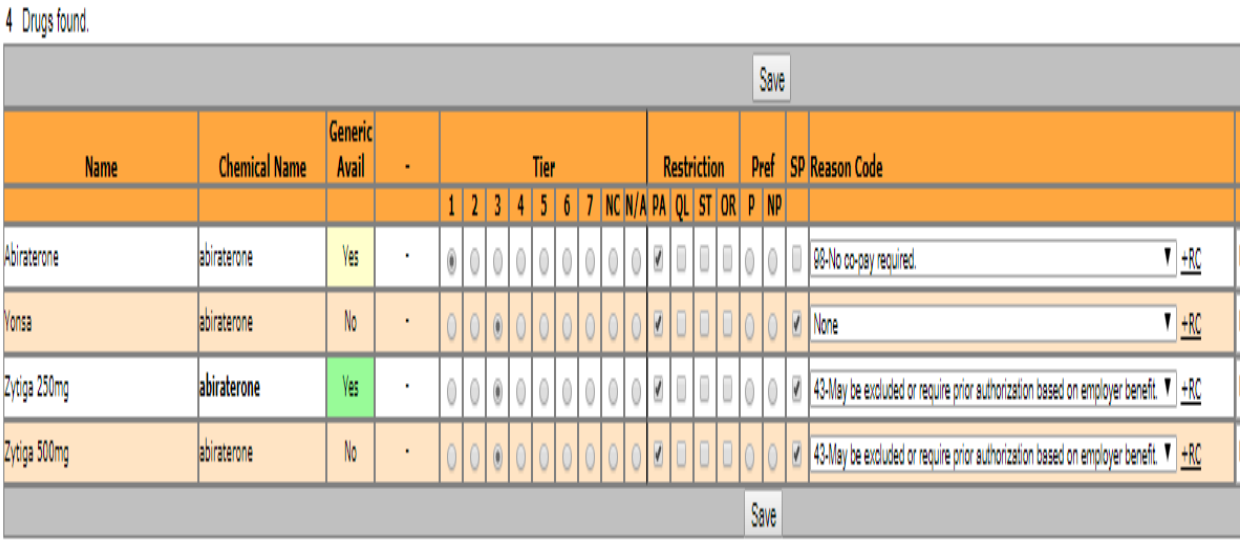


We can search drugs by-

- Drug Class
- Drug Name
- Drug ID
- Brand or Generic

How Fingertip Cover Drugs –

Based on the Plan type (Open or Closed) and drug type (Brand & Generic), Drugs needed to give their Tier Value or default value.


4 Drugs found.

Save

Name	Chemical Name	Generic Avail	-	Tier								Restriction				Pref		SP	Reason Code
				1	2	3	4	5	6	7	NC	N/A	PA	QL	ST	OR	P	NP	
Abiraterone	abiraterone	Yes	-	◉	○	○	○	○	○	○	○	○	☑	☐	☐	☐	○	○	☐	98-No co-pay required. +RC
Yonsa	abiraterone	No	-	○	○	◉	○	○	○	○	○	○	☑	☐	☐	☐	○	○	☑	None +RC
Zytiga 250mg	abiraterone	Yes	-	○	○	◉	○	○	○	○	○	○	☑	☐	☐	☐	○	○	☑	43-May be excluded or require prior authorization based on employer benefit. +RC
Zytiga 500mg	abiraterone	No	-	○	○	◉	○	○	○	○	○	○	☑	☐	☐	☐	○	○	☑	43-May be excluded or require prior authorization based on employer benefit. +RC

Save

Fingertip database storage page has Columns like –

- Drug name
- Chemical Name
- Generic available

- Tier status of drugs
- Restriction status of drugs
- SP status
- Reason codes

Reason codes are meant to justify such cases which are confusing or database not able to store those cases clearly.

Fingertip has database of 3 types of drugs –

1. Branded drugs

2.Generic drugs

3.Authorized generic drugs

Authorized generics are also known as Multi-source brand.Those drugs which are marketed by brand pharma companies under the Drug name similar to Brand name of drug,but marketed at generic drug prices.

Necessity of Reason Code-

1. When Multiple strength of a dosage form have multiple tier.

   Like Cialis 5mg has Tier 2 and Cialis 2.5mg has Tier 1.

   Then we need a reason code to justify multiple tiers depends on business rule.

2. When Multiple dosage forms of same drug have multiple tiers.

   Like tablet and capsule of same drugs have different tier.

Then we need a reason code to justify it, depends on business rule.

3. When Drug has Age restriction on formulary.

4. When drug has Gender restriction on formulary.

5. When Drug with same or different Tiers with presence of restrictions on only some strength.

Example 1- Here Linezolid has different dosage forms and Tablet form has Extra QL. So if Linezolid all dosage forms are present as Linezolid on Fingertip formulary. So we need to justify that QL does not apply to all dosage form.

Linezolid (100mg/5ml Suspension)	1	PA
Linezolid (600mg Tablet)	1	PA, QL
Linezolid (600mg/ 300ml Injection)	1	PA

So, we can code Linezolid as –

Tier 1, PA, QL, QL does not apply to all forms.

Example 2- If database has**Alprazolam for all dosage forms and strengths present here.**

Antianxiety Agents		
alprazolam er oral tablet extended release 24 hour	3	
alprazolam intensol oral concentrate	3	
alprazolam oral tablet	1	
alprazolam oral tablet dispersible	1	PA
alprazolam xr oral tablet extended release 24 hour	3	

Then we can code Alprazolam as –

Tier 1, PA, Tier status varies by strength, Tier status varies by dosage form, PA does not apply to all strengths, Pa does not apply to all dosage forms.

Note- Non-Self- administered drugs have Medical benefit always. So apart from coding a justification code should be applied, either it listed on formulary or not.

Like- **GAMMAGARD**(immune serums) needs a reason code as drug has medical benefit

Benefits of Fingertip formulary coding for Pharmaceutical Companies (Clients) –

- FF provides instant changes in formulary. So, client pharma companies have edge in detailing about drugs over their competitors because there are more than 5000 health plans which are coded in fingertip formulary and it's not easy for pharmaceutical companies to identify instant changes in formulary for so many drugs in so many plans.

- FF provides a interactive interface which shows all the interpretation of coded data directly to the client companies. Interface currently used by company is Publisher.

- The coded data provide region-wise or state-wise distribution of drugs. It shows the most prevalent diseases in corresponding areas and these data are purchased by other healthcare analytics companies.

- It's not easy for pharma companies to make marketing strategies instantly after knowing the drug changes in so many health plans.

  To overcome this, marketing representatives get visual aidsdirectly on their accessed platform and these visual aids and some marketing strategies are made by automated system to save the client time.

CONCLUSION –

Drug formulay mainly includes brands and generics drugs under Tier system. Tier is directly related to the copay. Lesser Tier means lesser copay. Prior authorization, quantity limits, and step therapy are restrictions,needed before purchasing drugs for specific drugs mentioned in formulary.

P & T committee responsible for designing of Formulary.

Fingertip Formulary is used to store all the data of Tier and Co-pay for corresponding drugs. It provides instant information to the clients about drugs addition, deletion and any restriction changes in formulary.

Reference-

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FormularyUnitedhealth 2019,Availableat;https://www.uhccommunityplan.com/assets/plandocuments/2019/formulary/en/2019-TN-Formulary-H0251-002-EN.pdf

learning.decisionresourcesgroup.com