



# **Navigating insurance and patient assistance for chemotherapy and targeted therapies**

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# Disclosures

- I have no actual or potential financial conflicts of interest to disclose

# Objectives and Outcomes

Upon completion of this educational activity, you will be able to:

- Integrate 505b medication utilization into oncology cancer center treatment plans
- Navigate biosimilar formulary management, copay assistance, foundation, and patient assistance programs to eliminate practice and patient financial toxicity

# What are 505(b)(2) medications?

- 505(b)(2) drugs are modified versions of approved drugs that may be used for new and/or existing indications
- Contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use
- Allows for flexibility in the characteristics of the proposed product without having to conduct studies on what is already known about the product

# Drug Approval Pathways

Approval Pathway	Traditional 505(b)(1)	Hybrid 505(b)(2)	Generic 505(j)
Application Type	NDA	NDA	ANDA
Data Requirement	Preclinical + Clinical	+/- TE Data	Bioequivalence
Market Exclusivity	5 Years	3 Years	≤ 180 Days
Time to Market	10 Years	3 – 8 Years	10 Months – 3.5 Years
TE Rating?	N/A	Maybe	Yes

# 505(b)(2) Medications

Year	505(b)(2) Approvals	Other Approvals	Total NDA Approvals	% 505(b)(2)
2023	58	54	112	52%
2022	59	34	93	63%
2021	50	52	102	49%
2020	62	52	114	54%
2019	55	51	106	52%
2018	60	64	124	48%
2017	73	53	126	58%
2016	43	43	86	50%
2015	49	60	109	45%
Total	509	463	972	52%

# 505(b)(2) Medications

## Dosage Form

- Suboxone (buprenorphine/naloxone films)

## Strength

- Qbrelis (lisinopril oral solution)

## Administration Route

- Spravato (esketamine nasal spray)

## Administration Instructions

- Vivimusta (bendamustine solution for injection)

## Formulation

- Vivitrol (naltrexone extended-release injectable)

## Dosing Regimen

- Gralise (gabapentin extended-release)

## Active Ingredient(s)

- Treximet (sumatriptan + naproxen)

## Preparation Instructions

- Frindovyx (cyclophosphamide solution for injection)

## Indication

- Aduhelm (aducanumab)




# 505(b)(2) medications are



# What is a 505(b)(2) medication?

- A. Generic versions of approved medications, that must demonstrate bioequivalence to the reference listed drug
- B. Modified versions of approved drugs that may be used for new and/or existing indications
- C. Always therapeutically equivalent to the reference listed drug
- D. Difficult to bring to market, offer no benefit to patients or pharmaceutical companies, and are not routinely seen in pharmacy practice

# 505(b)(2) Integration Check List



- **FDA 505(b)(2) understanding**



- **Communicating therapeutic equivalency, compounding, and administration**



- **Documenting appropriate HCPCS code**



- **Clinically and financially selecting 505(b)(2) drugs vs generics**



- **Communication between various stakeholders with pharmacy, providers, nursing, and revenue cycle**

# Pemetrexed variability

	PEMFEXY® (pemetrexed injection) <sup>1</sup>	PEMRYDI RTU® (pemetrexed injection) <sup>3</sup>	AXTLE™ (pemetrexed) for injection <sup>4</sup>
Indicated for use in combination with pembrolizumab*	✓	✓	✗
Supplied in a multi-dose vial (Offering potential benefit of reducing waste)	✓	✗	✗
Reconstitution not required	✓	✓	✗ Requires reconstitution with 5% Dextrose
Reference-standard pemetrexed concentration (25 mg/mL) <sup>45</sup>	✓	✗ (10 mg/mL)	✓
Storage conditions for partially used vials	In refrigeration <sup>5</sup> for up to 28 days	Must discard	Discard unused portion after <b>24 hours</b>
Storage conditions following preparation	Store diluted up to <b>48 hours</b> in refrigeration or room temperature <sup>6</sup>	Store in IV bag up to <b>24 hours</b>	Store in refrigeration <sup>5</sup> up to <b>24 hours</b> from the time of reconstitution

<https://www.pemfexy.com/>

# Administration

Administration instructions including route and administration time may vary for 505(b)(2) medications



**Infusion  
Time**

**60 Minutes**

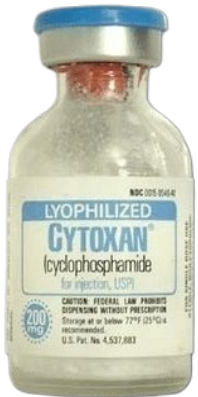
**20 Minutes**

**10 Minutes**

Image 4: [BENDEKA® \(bendamustine HCl\) injection](#)

# Clinical Use & Monitoring

505(b)(2) medications may have additional clinical considerations and monitoring requirements relating to patient populations



505(b)(1)RLD



505(j)AP



505(b)(2)ZC

Pharmacy Purchasing & Products Magazine Image 1: [Cytosoxan - Uses, Side Effects and Information - Welzo](#) Image 2: [Cyclophosphamide for Injection, USP | XGen Pharmaceuticals DJB, Incorporated](#) Image 3: [Cyclophosphamide Injection | Eugia US](#)

# Wholesale Procurement

- Identifying 505(b)(2) medications is difficult due to similarities in naming conventions, a lack of centralized data sources, and unclear designations on wholesaler web portals

NDC/UPC	GENERIC NAME	STRENGTH	FORM	SIZE	NET COST	CONTRACT
71288-0103-20	BENDAMUSTINE HCL	100MG	PWVL	1X1 EA	\$307.90	APXWAC
63459-0391-20	BENDAMUSTINE HCL	100MG	PWVL	1X1 EA	\$1,564.65	WACPVP
24338-0270-01	BENDAMUSTINE HCL	25MG/ML	MDPF	1X4 ML	\$974.61	WACPVP

# CMS Crosswalk

J9033	Inj, bendamustine hcl, 1mg	Accord Healthcare Inc	16729-0250-03	Bendamustine
J9033	Inj, bendamustine hcl, 1mg	Accord Healthcare Inc	16729-0251-05	Bendamustine
J9033	Inj, bendamustine hcl, 1mg	Eugia US LLC	55150-0391-01	Bendamustine Hydrochloride
J9033	Inj, bendamustine hcl, 1mg	Eugia US LLC	55150-0392-01	Bendamustine
J9033	Inj, bendamustine hcl, 1mg	Apotex Corp	60505-6095-00	Bendamustine Hydrochloride
J9033	Inj, bendamustine hcl, 1mg	Apotex Corp	60505-6096-00	Bendamustine
J9033	Inj, bendamustine hcl, 1mg	Cephalon, LLC	63459-0390-08	Treanda
J9033	Inj, bendamustine hcl, 1mg	Cephalon, LLC	63459-0391-20	Treanda
J9033	Inj, bendamustine hcl, 1mg	BluePoint Laboratories	68001-0572-41	Bendamustine
J9033	Inj, bendamustine hcl, 1mg	Meitheal Pharmaceuticals Inc.	71288-0102-10	Bendamustine
J9033	Inj, bendamustine hcl, 1mg	Meitheal Pharmaceuticals Inc.	71288-0103-20	Bendamustine
J9034	Inj., bendeka 1 mg	Cephalon, LLC	63459-0348-04	Bendeka
J9036	Inj. belrapzo/bendamustine	Baxter Healthcare Corporation	10019-0079-01	Bendamustine Hydrochloride
J9036	Inj. belrapzo/bendamustine	Eagle Pharmaceuticals, Inc.	42367-0521-25	Belrapzo
J9036	Inj. belrapzo/bendamustine	Apotex Corp	60505-6228-00	Bendamustine Hydrochloride
J9056	Inj, vivimusta, 1 mg	Azurity Pharmaceuticals Inc.	24338-0270-01	Vivimusta
J9056	Inj, vivimusta, 1 mg	Slayback Pharma LLC	71225-0120-01	Vivimusta



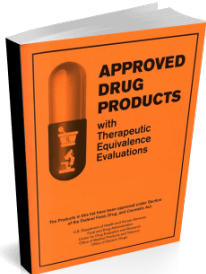
<https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files>

# Orange Book

The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information.

## Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Search Results for Proprietary Name, Active Ingredient or Application Number: *bendamustine*

☒ RX ☒ OTC ☒ DISCN

Display  records per page

Showing 1 to 29 of 29 entries

[CSV](#) [Excel](#) [Print](#)

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HYDROCHLORIDE	A205574	POWDER	INTRAVENOUS	25MG/VIAL	AP			ACCORD HEALTHCARE INC
RX	BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HYDROCHLORIDE	A205376	POWDER	INTRAVENOUS	25MG/VIAL	AP			DR REDDYS LABORATORIES LTD
RX	BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HYDROCHLORIDE	A214739	POWDER	INTRAVENOUS	25MG/VIAL	AP			EUGIA PHARMA SPECIALITIES LTD
RX	BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HYDROCHLORIDE	A211001	POWDER	INTRAVENOUS	25MG/VIAL	AP			MEITHEAL PHARMACEUTICALS INC
RX	BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HYDROCHLORIDE	A205574	POWDER	INTRAVENOUS	100MG/VIAL	AP			ACCORD HEALTHCARE INC
RX	BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HYDROCHLORIDE	A205376	POWDER	INTRAVENOUS	100MG/VIAL	AP			DR REDDYS LABORATORIES LTD
RX	BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HYDROCHLORIDE	A214739	POWDER	INTRAVENOUS	100MG/VIAL	AP			EUGIA PHARMA SPECIALITIES LTD
RX	BENDAMUSTINE HYDROCHLORIDE	BENDAMUSTINE HYDROCHLORIDE	A211001	POWDER	INTRAVENOUS	100MG/VIAL	AP			MEITHEAL PHARMACEUTICALS INC
RX	BENDAMUSTINE	TRFANDA	N022249	POWDER	INTRAVENOUS	25MG/VIAL	AP	RI D	RS	CFPHAI ON INC



# EHR Considerations

Drug databases, referenced by electronic health record systems, may assume therapeutic equivalency and consolidate medications with similar features into one medical record

## BENDAMUSTINE HCL 100 MG/4ML IV SOLN [131577] [Edit Medication](#)

M	D	P	Package	Count	Pkg. Size	Description	Medication	P..	C..	U..	Manufacturer
✓	●		10019-079-01	1	4 mL	Vial	BENDAMUSTINE HCL 100 MG/4ML IV SOLN	B...	S...		BAXTER HEALTHCARE CORPORATION
			24338-270-01	1	4 mL	Vial	VIVIMUSTA 100 MG/4ML IV SOLN	B...	S...		AZURITY PHARMACEUTICALS
			42367-521-25	1	4 mL	Vial	BELRAPZO 100 MG/4ML IV SOLN	B...	S...		EAGLE PHARMACEUTICALS
			60505-6228-0	1	4 mL	Vial	BENDAMUSTINE HCL 100 MG/4ML IV SOLN	B...	S...		APOTEX
✓			63459-348-04	1	4 mL	Vial	BENDEKA 100 MG/4ML IV SOLN	B...	S...		TEVA PHARMACEUTICALS USA
✓			71225-120-01	1	4 mL	Vial	VIVIMUSTA 100 MG/4ML IV SOLN	B...	S...		AZURITY PHARMACEUTICALS

# Formulary Considerations

**Interchangeability**

**Advantages**

**Differences**

**EHR  
Implementation**

**Billing Integrity**

**Procurement**

**Cost Efficacy**

[Pharmacy Purchasing & Products Magazine](#)



## 505(b)(2) management considerations:

# 505(b)(2) considerations:

- A. Maintain crosswalk data to ensure appropriate HCPCS data
- B. Review administration and formulation differences between 505(b)(2) and generic drugs
- C. Utilize Orange Book and CMS as resources during P&T review
- D. All of the above

# Clinical Consequences



**Mr. Jones is a 68 YO M w/PMH of HTN, anxiety, T2DM, and NHL presenting to receive infusion therapy with bendamustine + rituximab (BR).**

**Today, Mr. Jones begins C3D1...**

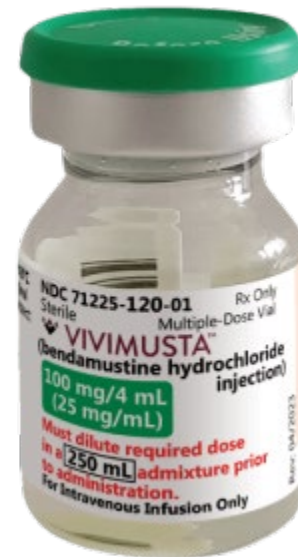
# Continued



**As Mr. Jones continues his bendamustine infusion, he becomes increasingly restless and begins clearing his throat**

**Another 15 minutes pass, and Mr. Jones develops significant facial flushing, dyspnea, and hypotension**

# Culprit



# Financial Consequences

## Incorrectly Assigned HCPCS Codes

- **Denied Claims**
- **Delayed Reimbursement**
- **Financial Burdens for Patients & Institutions**

## Reasons for Claim Denial

**Incorrect  
HCPCS  
Code**

**Incorrect  
Product  
Dispensed**

**No Prior  
Authorization**

**Payer  
Restrictions**



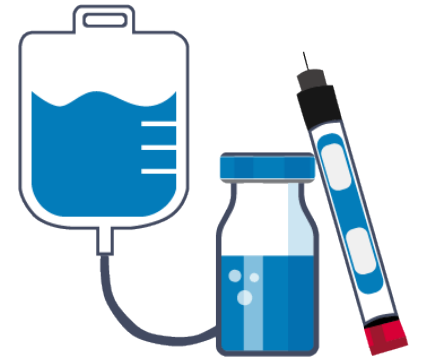
# Strategies for Success

- **Robust P&T Process for 505(b)(2) drugs**
- **Communication between stakeholders**
- **EHR Crosswalk of data (inventory to authorization to operations)**
- **Education of all stakeholders handling 505(b)(2) products**
- **Revenue cycle support**

# What is a biosimilar?

- A biosimilar and its original biologic are made from the same types of sources – and have the same treatment risks and benefits.
- Biosimilars are a type of biologic medication that is safe and effective for treating many illnesses.
- A biosimilar and its original biologic have the same treatment risks and benefits.
- Biosimilars may be available at a lower cost than the original biologics.
- Substitution and interchangeability between products mitigates some of the issues that plague 505(b)(2)

<https://www.fda.gov/drugs/biosimilars/biosimilars-basics-patients>



# Biosimilar Management

- Adoption of a preferred biosimilar is mainly driven by payer policies
- Cost
- Reimbursement
- How to succeed:
  - Adopt multiple biosimilars to formulary that satisfy the diverse market of commercial and government payers
  - Review your payer landscape and adopt the most widely covered product as your preferred option
  - Maintain open lines of communication between inventory, authorization, clinic, and operations teams to ensure what is stocked vs authorized vs ordered align

***Alymsys (bevacizumab-maly)***

*BLA Number: 761231*

***Avastin (bevacizumab)***

*BLA Number: 125085*

***Avzivi (bevacizumab-tnjn)***

*BLA Number: 761198*

***Jobevne (bevacizumab-nwgd)***

*BLA Number: 761175*

***Mvasi (bevacizumab-awwb)***

*BLA Number: 761028*

***Vegzelma (bevacizumab-adcd)***

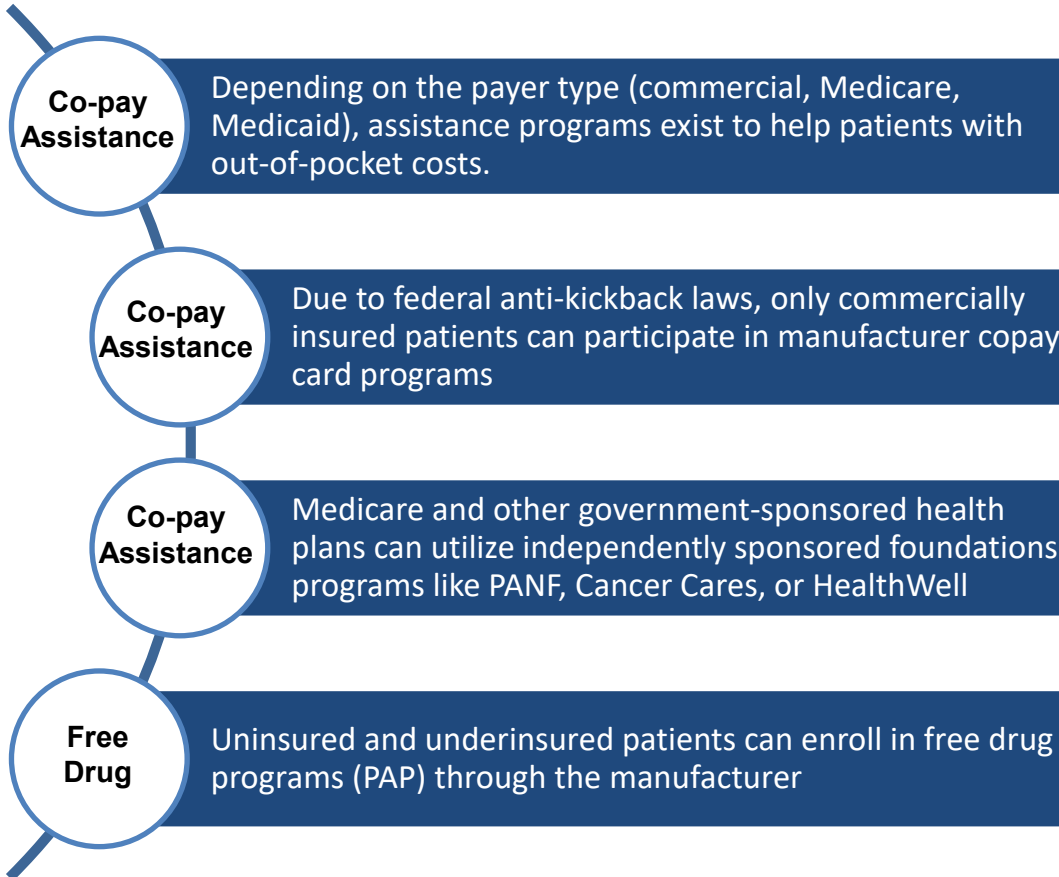
*BLA Number: 761268*

***Zirabev (bevacizumab-bvzr)***

*BLA Number: 761099*

<https://purplebooksearch.fda.gov/>

# Patient Assistance Programs



# Managing Programs

- PAP
  - Identify and enroll patients
  - Flag patients
  - Obtain inventory (upfront/replacement)
  - Utilize patient specific inventory
  - Adjust cost
- Copay
  - Identify commercial patients on copay card eligible therapy
  - Document copay program as 2ndary insurance in registration
  - Track claims with associated CPT/HCPSCS for primary ins payment
  - Submit EOB to program and pass off to patient/rev cycle to charge copay card credit card/request virtual check
- Foundation
  - Identify underinsured medicare (part B only or advantage plan)
  - Sort and track patients by diagnosis
  - Daily or weekly review foundation sites for open disease funds
  - Enroll and pass off details of foundation to patient to utilize to pay bills/rev cycle bill appropriate cancer associated claims/EOBs



**A patient calls the office regarding a high copay on their Keytruda due deductible resetting at the 1st of the year. What would be the most appropriate program to help them enroll into?**

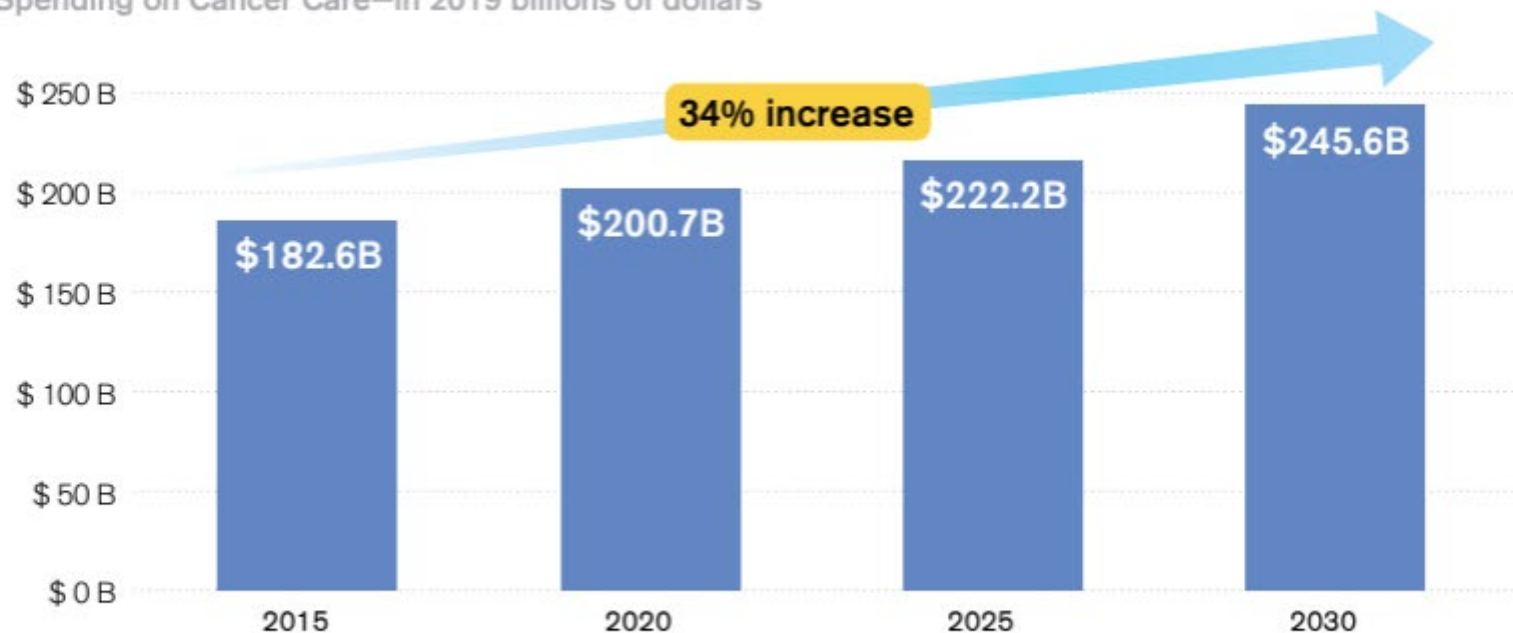
# Patient Case

- A patient calls the office regarding a high copay on their Keytruda due deductible resetting at the 1st of the year. What would be the most appropriate program to help them enroll into?
- A. Foundation
- B. Manufacturer PAP/free drug program
- C. Copay Card
- D. GoodRX

# Oncology Healthcare Trends

National  
Cancer  
Costs  
Projected  
to Increase  
Drastically  
by 2030

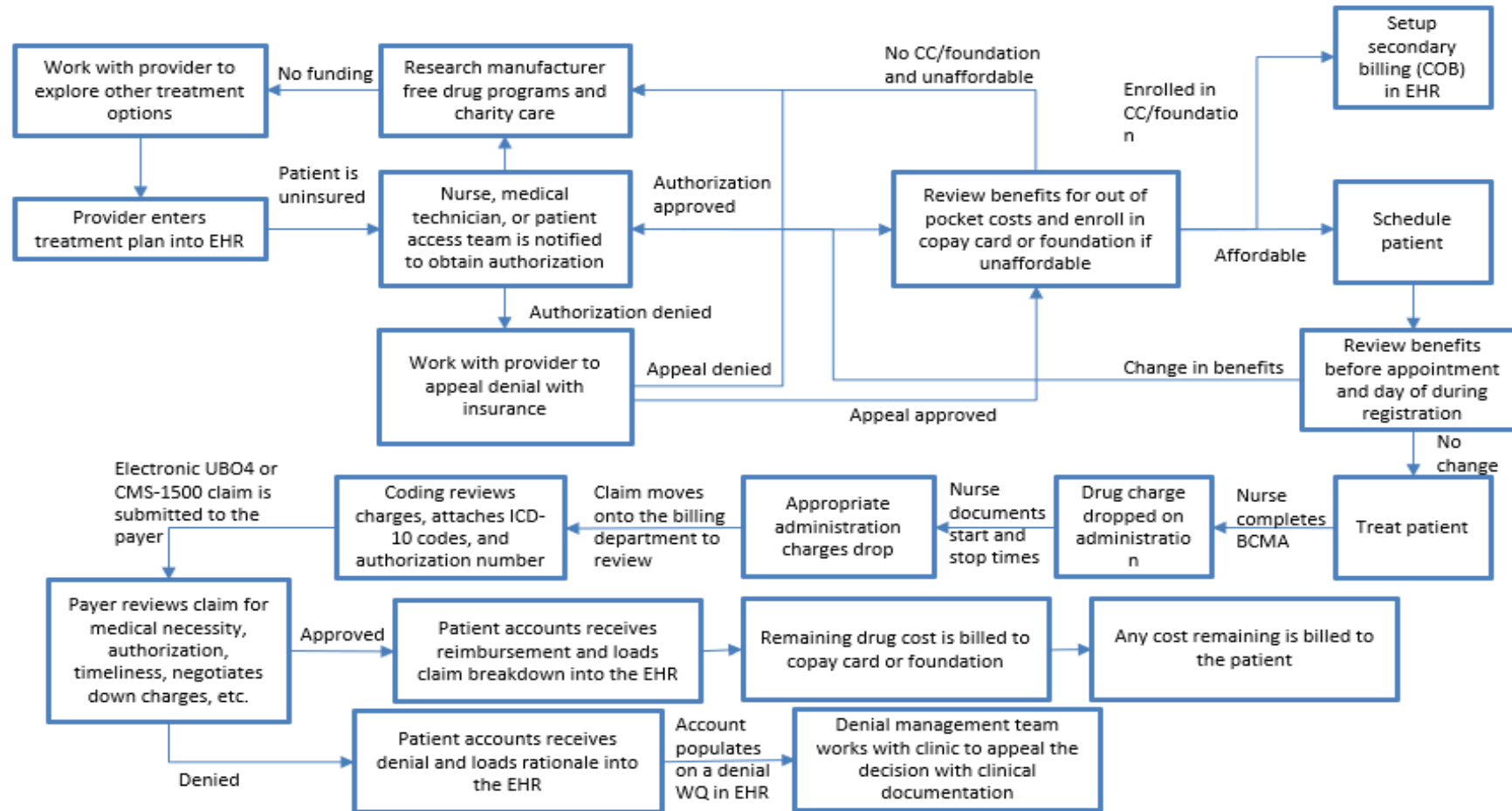
Spending on Cancer Care—in 2019 billions of dollars



Source: Mariotto AB, Enewold L, Zhao J, Zeruto CA, Yabroff KR. Medical Care Costs Associated with Cancer Survivorship in the United States. Cancer Epidemiol Biomarkers Prev June 10 2020 DOI: 10.1158/1055-9965.EPI-19-1534



# Complexity of Providing Care





THANK YOU!