



**Therapeutics Update:**

# **Important New Drugs and Their Underwriting Implications**

American Academy of Insurance Medicine – October 16, 2023



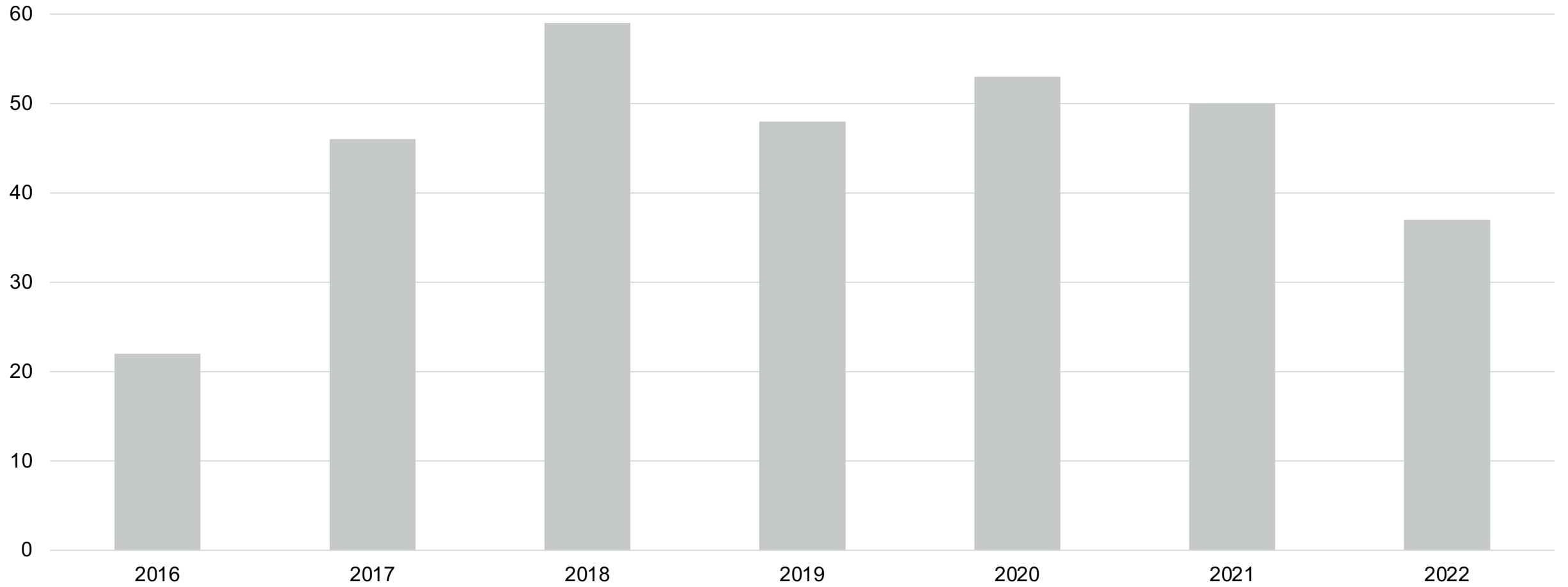
# LEARNING OBJECTIVES

- Review trends in novel drug approvals by the FDA over the years
- Discuss ways to identify and interpret new drugs during the underwriting process
- Highlight newly FDA-approved drugs and review their underwriting implications

# NOVEL DRUG APPROVALS DECREASED IN 2022.

---

Novel Drugs FDA-Approved by Year



# MEDICATION BILLING VARIES.

---

Adjudication of drug claims may occur via the prescription benefit or medical benefit.

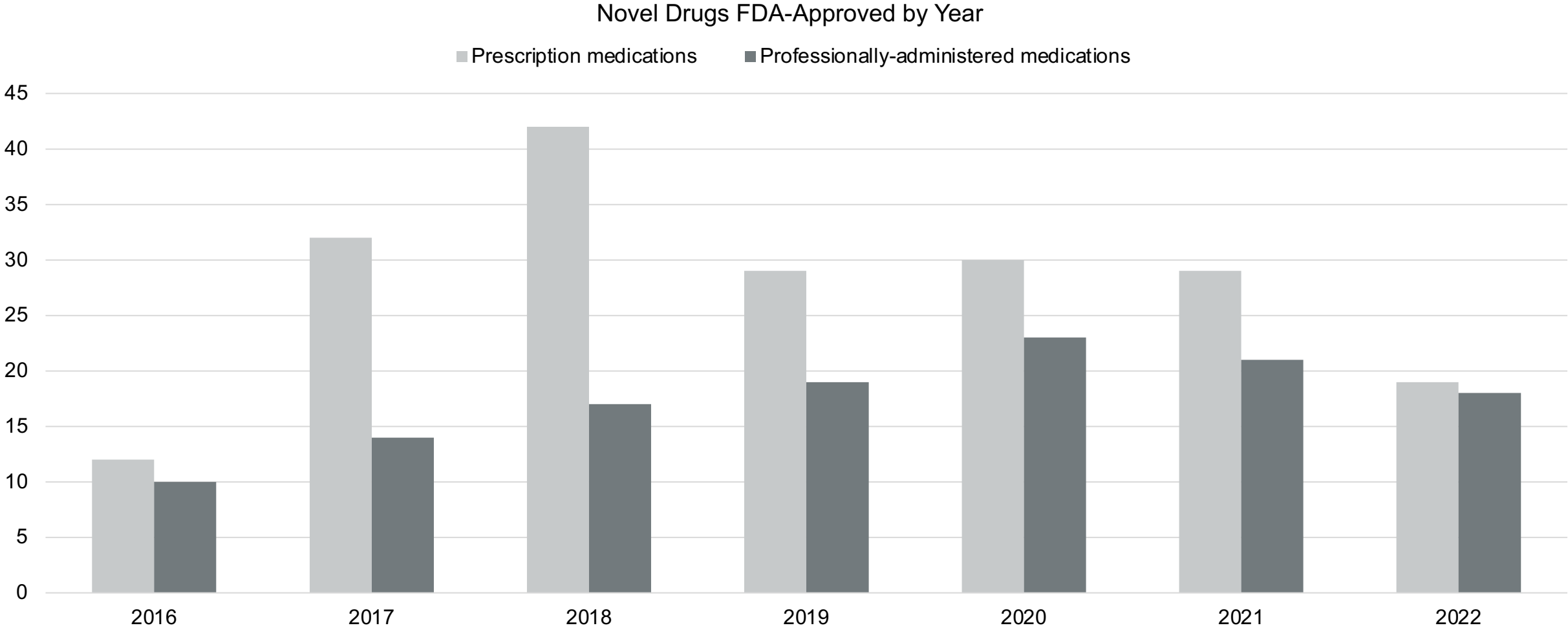
## PRESCRIPTION CLAIMS

- Medications picked up from an outpatient pharmacy
  - Oral
  - Topical
  - Self-administered injections
- Paid for by pharmacy benefit

## MEDICAL CLAIMS

- Medications administered in a healthcare setting
  - Intravenous infusions
  - Chemotherapy
  - Complex products (e.g., gene therapy, CAR-T)
- Paid for by medical benefit

# MEDICAL DATA IS CRUCIAL FOR INSIGHT INTO NEW MEDICATIONS.





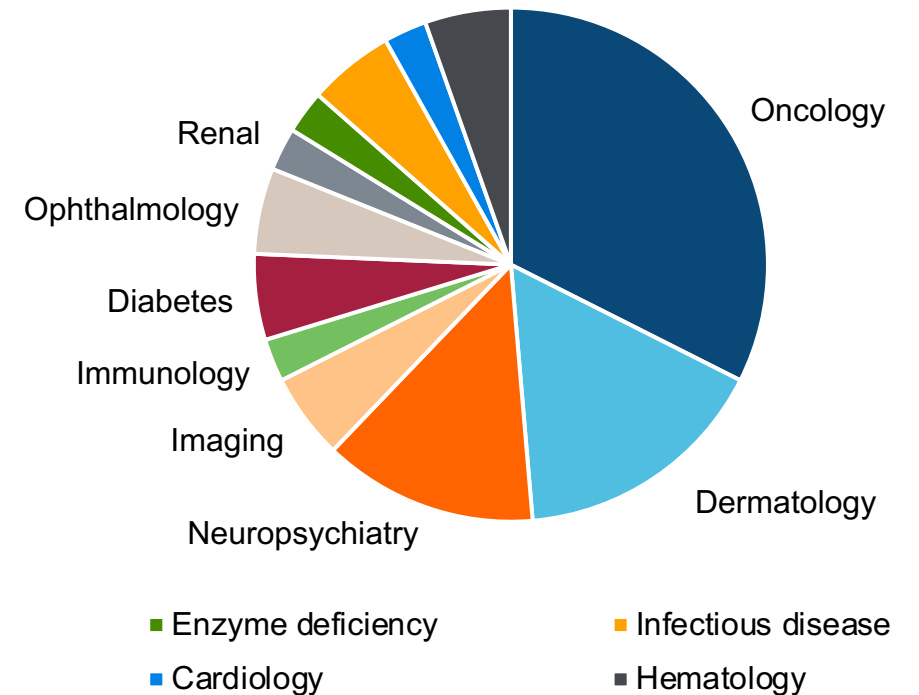
# CANCER

# TWELVE CANCER-RELATED DRUGS WERE APPROVED IN 2022.

## Cancer remains a top disease target for new therapeutics

- Frequent approvals likely to continue
  - Treatment addresses unmet needs
  - Often approved through accelerated pathways
- Most new approvals are used in advanced disease
- Identification of cancer treatment can be challenging

New Drugs by Category, 2022



# CANCER TREATMENT ISN'T TYPICALLY FOUND IN A PHARMACY.

Age: 61 | Gender: F

Application date: 9/2022

Prescription Fills: 51

Medical Codes: 1834





# CANCER TREATMENT ISN'T TYPICALLY FOUND IN A PHARMACY.

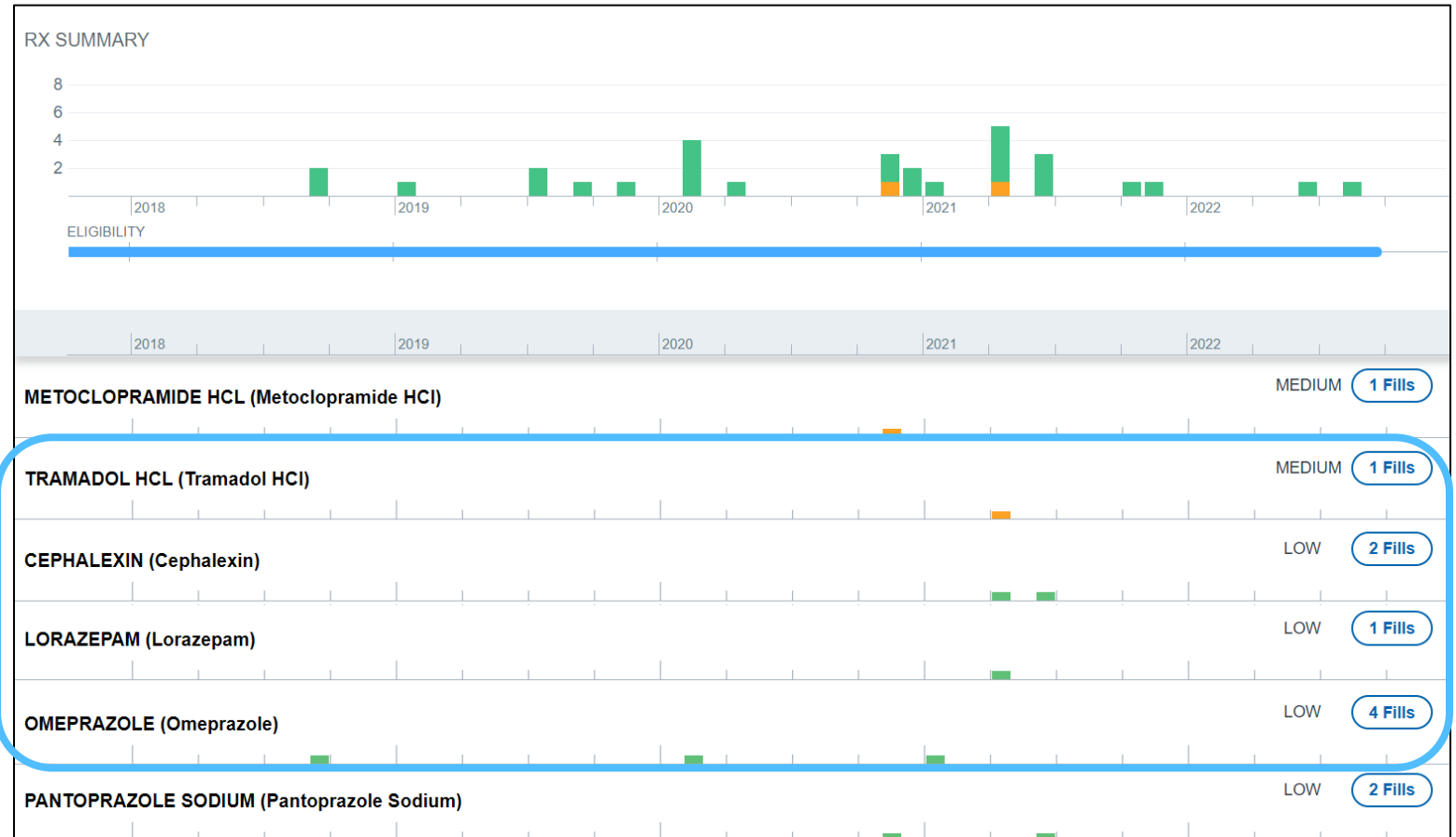
Age: 61 | Gender: F

Application date: 9/2022

Prescription Fills: 51

Medical Codes: 1834

DRUGS	
CEPHALEXIN	● 1 Fill
FLUCONAZOLE	● 1 Fill
LORAZEPAM	● 1 Fill
OMEPRAZOLE	● 1 Fill
TRAMADOL HCL	■ 1 Fill



# CHEMOTHERAPY IS BILLED THROUGH THE MEDICAL BENEFIT.

Age: 61 | Gender: F

Application date: 9/2022

Prescription Fills: 51

Medical Codes: 1834

SERVICE DATES	PROVIDER	CLAIM DETAILS
10/05/2021 - 10/21/2021	SUBMITTED PROVIDER [REDACTED] 022 - On Campus-Outpatient Hospital	<b>DIAGNOSIS</b> Encounter for antineoplastic chemotherapy ICD-10 Z51.11 Malignant neoplasm of body of stomach ICD-10 C16.2 Encounter for other procedures for purposes other than remedying health state ICD-10 Z41.8
		<b>PROCEDURE</b> Comprehensive metabolic panel CPT-4 80053 Carcinoembryonic antigen (CEA) CPT-4 82378 Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count CPT-4 85025 Injection, aprepitant, 1 mg(340B ACQUIRED DRUG) HCPCS J0185 Injection, leucovorin calcium, per 50 mg HCPCS J0640 Injection, dexamethasone sodium phosphate, 1 mg HCPCS J1100 Injection, palonosetron hcl, 25 mcg HCPCS J2469 Injection, fluorouracil, 500 mg HCPCS J9190 Injection, oxaliplatin, 0.5 mg HCPCS J9263 Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg.(TRACKING 340B ACQUIRED DRUG) HCPCS Q5111 Pharmacy: IV solutions REV 0258

Encounter for antineoplastic chemotherapy  
Malignant neoplasm of body of stomach

Injection, fluorouracil, 500 mg  
Injection, oxaliplatin, 0.5 mg  
Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg.(TRACKING 340B ACQUIRED DRUG)

# DIAGNOSIS CODES PROVIDE INSIGHT INTO NON-SPECIFIC DRUGS.

Age: 61 | Gender: F

Application date: 9/2022

Prescription Fills: 51

Medical Codes: 1834

SERVICE DATES	PROVIDER	CLAIM DETAILS
06/07/2022 - 06/07/2022	SUBMITTED PROVIDER [REDACTED] 022 - On Campus-Outpatient Hospital	DIAGNOSIS
		Secondary malignant neoplasm of retroperitoneum and peritoneum ICD-10 C78.6
		Malignant neoplasm of stomach, unspecified ICD-10 C16.9
		Secondary malignant neoplasm of pleura ICD-10 C78.2
		Unspecified abdominal pain ICD-10 R10.9
		PROCEDURE
		Collection of venous blood by venipuncture CPT-4 36415
		Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance CPT-4 49083
		Not otherwise classified, antineoplastic drugs HCPCS J9999
		Pharmacy REV 0250
Medical/Surgical Supplies: Sterile supplies REV 0272		
[REDACTED] 034 - Hospice	[REDACTED]	DIAGNOSIS
		Malignant neoplasm of stomach, unspecified ICD-10 C16.9
		Personal history of other diseases of the nervous system and sense organs ICD-10 Z86.69
		PROCEDURE
		Services of clinical social worker in home health or hospice settings, each 15 minutes HCPCS G0155
		Direct skilled nursing services of a registered nurse (rn) in the home health or hospice setting, each 15 minutes HCPCS G0299
		Hospice or home health care provided in patient's home/residence HCPCS Q5001

Not otherwise classified, antineoplastic drugs J9999

# DIAGNOSIS CODES PROVIDE INSIGHT INTO NON-SPECIFIC DRUGS.

Age: 61 | Gender: F

Application date: 9/2022

Prescription Fills: 5

Medical Codes: 183

SERVICE DATES	PROVIDER	CLAIM DETAILS																											
06/07/2022 - 06/07/2022	SUBMITTED PROVIDER [REDACTED] 022 - On Campus-Outpatient Hospital	<p><b>DIAGNOSIS</b></p> <table border="1"> <tr> <td>Secondary malignant neoplasm of retroperitoneum and peritoneum</td> <td>ICD-10</td> <td>C78.6</td> </tr> <tr> <td>Malignant neoplasm of stomach, unspecified</td> <td>ICD-10</td> <td>C16.9</td> </tr> <tr> <td>Secondary malignant neoplasm of pleura</td> <td>ICD-10</td> <td>C78.2</td> </tr> <tr> <td>Unspecified abdominal pain</td> <td>ICD-10</td> <td>R10.9</td> </tr> </table> <p><b>PROCEDURE</b></p> <table border="1"> <tr> <td>Collection of venous blood by venipuncture</td> <td>CPT-4</td> <td>36415</td> </tr> <tr> <td>Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance</td> <td>CPT-4</td> <td>49083</td> </tr> <tr> <td>Not otherwise classified, antineoplastic drugs</td> <td>HCPCS</td> <td>J9999</td> </tr> <tr> <td>Pharmacy</td> <td>REV</td> <td>0250</td> </tr> <tr> <td>Medical/Surgical Supplies: Sterile supplies</td> <td>REV</td> <td>0272</td> </tr> </table>	Secondary malignant neoplasm of retroperitoneum and peritoneum	ICD-10	C78.6	Malignant neoplasm of stomach, unspecified	ICD-10	C16.9	Secondary malignant neoplasm of pleura	ICD-10	C78.2	Unspecified abdominal pain	ICD-10	R10.9	Collection of venous blood by venipuncture	CPT-4	36415	Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance	CPT-4	49083	Not otherwise classified, antineoplastic drugs	HCPCS	J9999	Pharmacy	REV	0250	Medical/Surgical Supplies: Sterile supplies	REV	0272
Secondary malignant neoplasm of retroperitoneum and peritoneum	ICD-10	C78.6																											
Malignant neoplasm of stomach, unspecified	ICD-10	C16.9																											
Secondary malignant neoplasm of pleura	ICD-10	C78.2																											
Unspecified abdominal pain	ICD-10	R10.9																											
Collection of venous blood by venipuncture	CPT-4	36415																											
Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance	CPT-4	49083																											
Not otherwise classified, antineoplastic drugs	HCPCS	J9999																											
Pharmacy	REV	0250																											
Medical/Surgical Supplies: Sterile supplies	REV	0272																											
06/27/2022 - 06/29/2022	SUBMITTED PROVIDER [REDACTED] 034 - Hospice	<p><b>DIAGNOSIS</b></p> <table border="1"> <tr> <td>Malignant neoplasm of stomach, unspecified</td> <td>ICD-10</td> <td>C16.9</td> </tr> <tr> <td>Personal history of other diseases of the nervous system and sense organs</td> <td>ICD-10</td> <td>Z86.69</td> </tr> </table> <p><b>PROCEDURE</b></p> <table border="1"> <tr> <td>Services of clinical social worker in home health or hospice settings, each 15 minutes</td> <td>HCPCS</td> <td>G0155</td> </tr> <tr> <td>Direct skilled nursing services of a registered nurse (rn) in the home health or hospice setting, each 15 minutes</td> <td>HCPCS</td> <td>G0299</td> </tr> <tr> <td>Hospice or home health care provided in patient's home/residence</td> <td>HCPCS</td> <td>Q5001</td> </tr> </table>	Malignant neoplasm of stomach, unspecified	ICD-10	C16.9	Personal history of other diseases of the nervous system and sense organs	ICD-10	Z86.69	Services of clinical social worker in home health or hospice settings, each 15 minutes	HCPCS	G0155	Direct skilled nursing services of a registered nurse (rn) in the home health or hospice setting, each 15 minutes	HCPCS	G0299	Hospice or home health care provided in patient's home/residence	HCPCS	Q5001												
Malignant neoplasm of stomach, unspecified	ICD-10	C16.9																											
Personal history of other diseases of the nervous system and sense organs	ICD-10	Z86.69																											
Services of clinical social worker in home health or hospice settings, each 15 minutes	HCPCS	G0155																											
Direct skilled nursing services of a registered nurse (rn) in the home health or hospice setting, each 15 minutes	HCPCS	G0299																											
Hospice or home health care provided in patient's home/residence	HCPCS	Q5001																											

Secondary malignant neoplasm of retroperitoneum and peritoneum

Malignant neoplasm of stomach, unspecified

Secondary malignant neoplasm of pleura

034 - Hospice



# DIABETES

# **TWO NOVEL ANTIDIABETIC AGENTS WERE APPROVED IN 2022.**

## **Tzielid (teplizumab-mzwv)**

- Delays onset of type 1 diabetes
- Precursor to insulin

Type 1

## **Mounjaro (tirzepatide)**

- Mechanism builds upon existing GLP-1 agonists (e.g., Ozempic, Trulicity, Victoza)
- Significant A1c reduction and weight loss

Type 2

# TYPE 1 DIABETES DEVELOPS OVER TIME.

---

## Stage 1

- **Autoantibodies attacking insulin-creating beta cells**
- Blood sugar remains normal
- No symptoms

## Stage 2

- Autoantibodies attacking insulin-creating beta cells
- **Blood sugar is abnormal**
- No symptoms

## Stage 3

- Significant beta cell loss
- Blood sugar is abnormal
- **Symptoms present**

### Symptoms may include:

- Increased thirst/urination
- Unexplained weight loss
- Fatigue

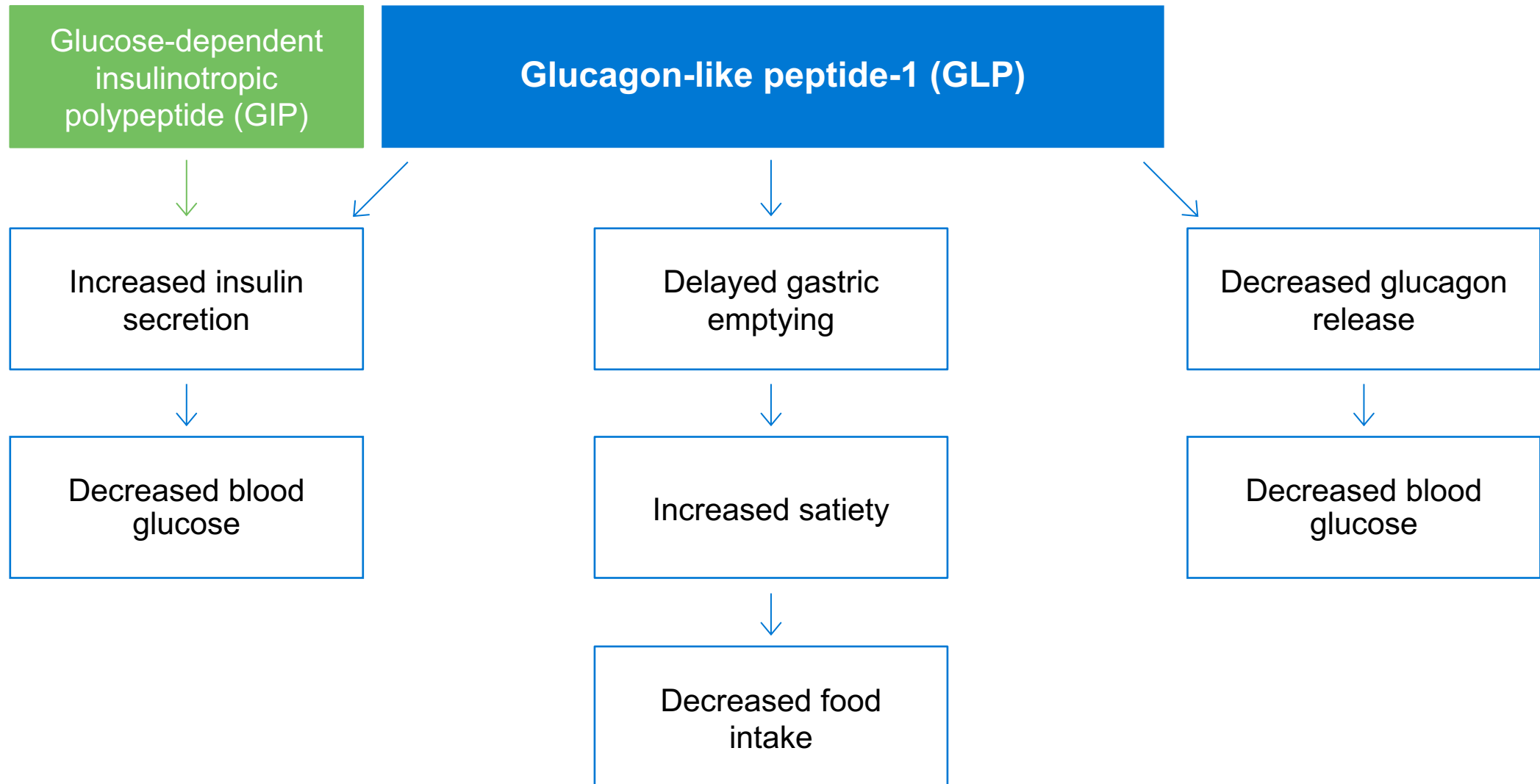
# **TZIELD DELAYS INEVITABLE TYPE 1 DIABETES SYMPTOMS.**

## **TZIELD (teplizumab-mzwv)**

- Used to delay onset of type 1 diabetes stage 3
  - Delays onset by two years
- Binds to immune cells and prevents destruction of beta cells
- Most often used by juveniles
  - 66% of study participants were under age 18



# MOUNJARO BUILDS UPON THE ACTION OF GLP-1 AGONISTS.



# **MOUNJARO IS ALREADY SEEING SIGNIFICANT USE.**

---

## **MOUNJARO (tirzepatide)**

- Used to treat type 2 diabetes
- Mimics action of GLP-1 and GIP hormones
- Reduces A1c by 2.3% and weight by 25 pounds
- Seeking approval for use in obesity

# GLP-1 AGONISTS AREN'T JUST FOR DIABETES ANYMORE.

---

## Obesity formulation

Wegovy

Saxenda

RM <100%

## Generic name

Semaglutide

Liraglutide

## Diabetes formulation

Rybelsus / Ozempic

Victoza

RM 140%–160%

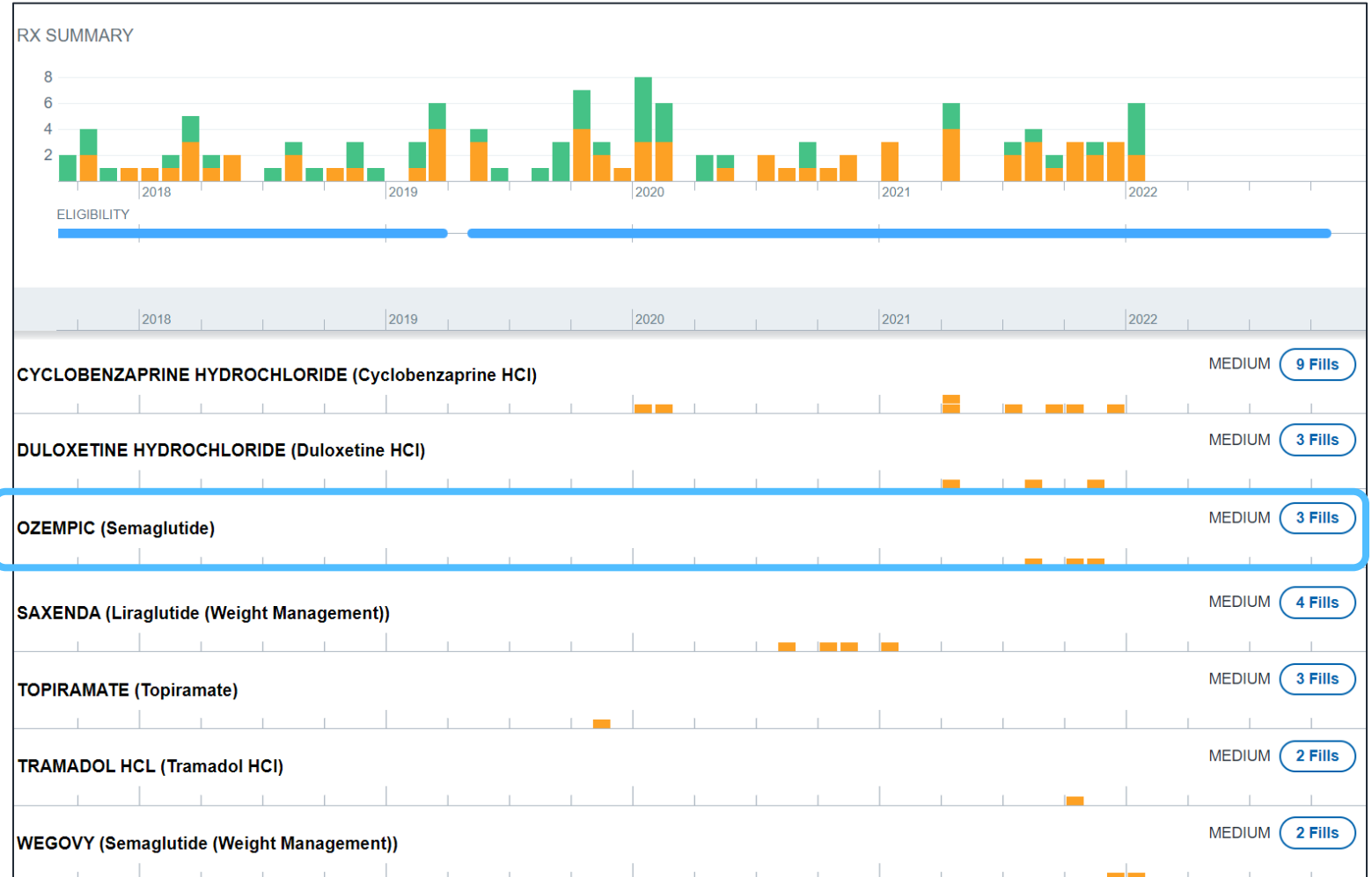
# OFF-LABEL USE OF GLP-1 AGONISTS MAY BECOME PREVALENT.

Age: 42 | Gender: F

Application date: 10/2022

Prescription Fills: 148

Medical Codes: 374



# OFF-LABEL USE OF GLP-1 AGONISTS MAY BECOME PREVALENT.

Age: 42 | Gender: F

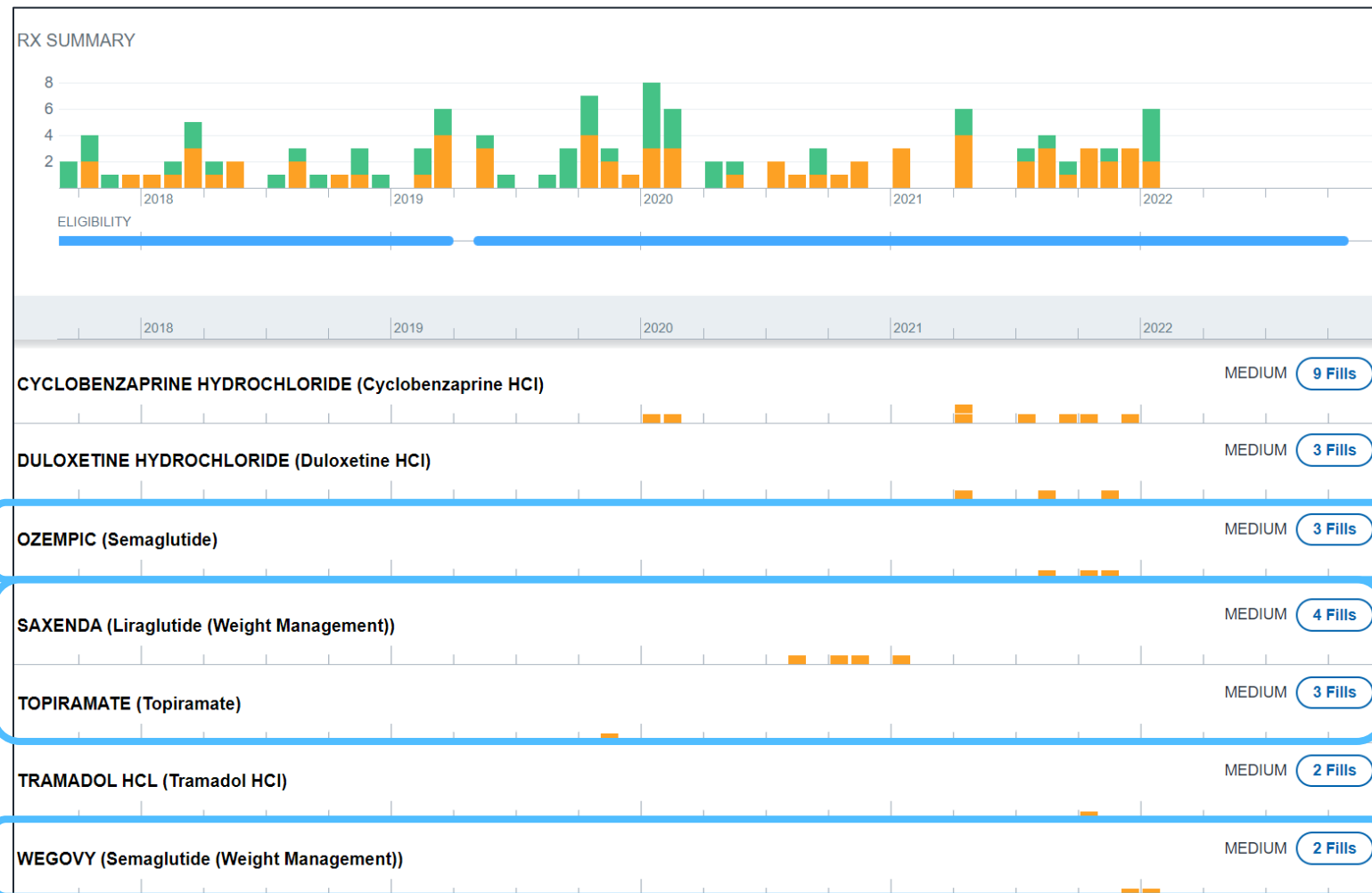
Application date: 10/2022

Prescription Fills: 148

Medical Codes: 374

Relative mortality

<100%



# OFF-LABEL USE OF GLP-1 AGONISTS MAY BECOME PREVALENT.

Age: 42 | Gender: F

Application date: 10/2022

Prescription Fills: 148

Medical Codes: 374

SERVICE DATES	PROVIDER	CLAIM DETAILS
02/05/2018 - 02/05/2018	SUBMITTED PROVIDER	DIAGNOSIS
	[REDACTED] 011 - Office	Pelvic and perineal pain ICD-10 R10.2 <b>Obesity, unspecified ICD-10 E66.9</b> Excessive and frequent menstruation with irregular cycle ICD-10 N92.1
	CURRENT PROVIDER	PROCEDURE
	[REDACTED] 011 - Office	Office or other outpatient visit for the evaluation and management of an established patient, usually the presenting problem(s) are of moderate to high severity. Typically 25 minutes are spent face-to-face with the patient and/or family. (Significant, Separately Identifiable E&M Service by the Same Physician on the Same Day of a Procedure or Other Service) CPT-4 99214 Ultrasound, transvaginal CPT-4 76830

Obesity, unspecified



# DERMATOLOGIC

2023 – Washington, DC

# FORMULATION MATTERS - ROFLUMILAST

---

New applications of existing ingredients can be used for new indications.

## ORAL - Daliresp

- Used in severe COPD
- Generally reserved for persistent exacerbations despite triple therapy with inhalers

Relative mortality

>400%

## TOPICAL - Zoryve

- Used in plaque psoriasis
- Likely to see other topical agents (e.g., steroids, calcipotriene, tacrolimus) or phototherapy prior to use

Relative mortality

Estimated ~100%



# FORMULATION MATTERS - RUXOLITINIB

---

New applications of existing ingredients can be used for new indications.

## ORAL - Jakafi

- Used in graft-vs-host disease, myelofibrosis, polycythemia vera
- Likely to see other agents used first depending on condition

Relative mortality

>600%

## TOPICAL - Opzelura

- Used in dermatologic conditions, namely atopic dermatitis and vitiligo
- May be used first-line

Relative mortality

Estimated ~100%

# SEVERE PSORIASIS CAN BE DIFFERENTIATED USING MEDICATIONS.

## Mild to Moderate Activity

### VTAMA (tapinarof)

- Topical cream
- Likely to compete with topical steroids
- Fewer side effects
- Being studied in atopic dermatitis

Relative mortality

Estimated ~100%

## Moderate to Severe Activity

### SOTYKTU (deucravacitinib)

- Oral tablet
- Studied against Otezla (apremilast)
  - 10%–20% greater likelihood of skin clearance
  - More tolerable
- Being studied in Crohn's disease, ulcerative colitis, psoriatic arthritis, lupus erythematosus

Relative mortality

Estimated ~150%

# NEW USES FOR OLD MEDICATIONS CONTINUE IN 2022.

## Indications for Select Autoimmune Drugs

	Axial spondyloarthritis	Atopic dermatitis	Crohn's disease	Plaque psoriasis	Psoriatic arthritis	Rheumatoid arthritis	Ulcerative colitis
Rinvoq (upadacitinib)					x	x	
Skyrizi (risankizumab)				x			
Stelara (ustekinumab)			x	x			x

# NEW USES FOR OLD MEDICATIONS CONTINUE IN 2022.

## Indications for Select Autoimmune Drugs

	Axial spondyloarthritis	Atopic dermatitis	Crohn's disease	Plaque psoriasis	Psoriatic arthritis	Rheumatoid arthritis	Ulcerative colitis
Rinvoq (upadacitinib)	x*	x*			x	x	x*
Skyrizi (risankizumab)			x*	x	x*		
Stelara (ustekinumab)			x	x	x*		x

\*Represents new indication as of 2022

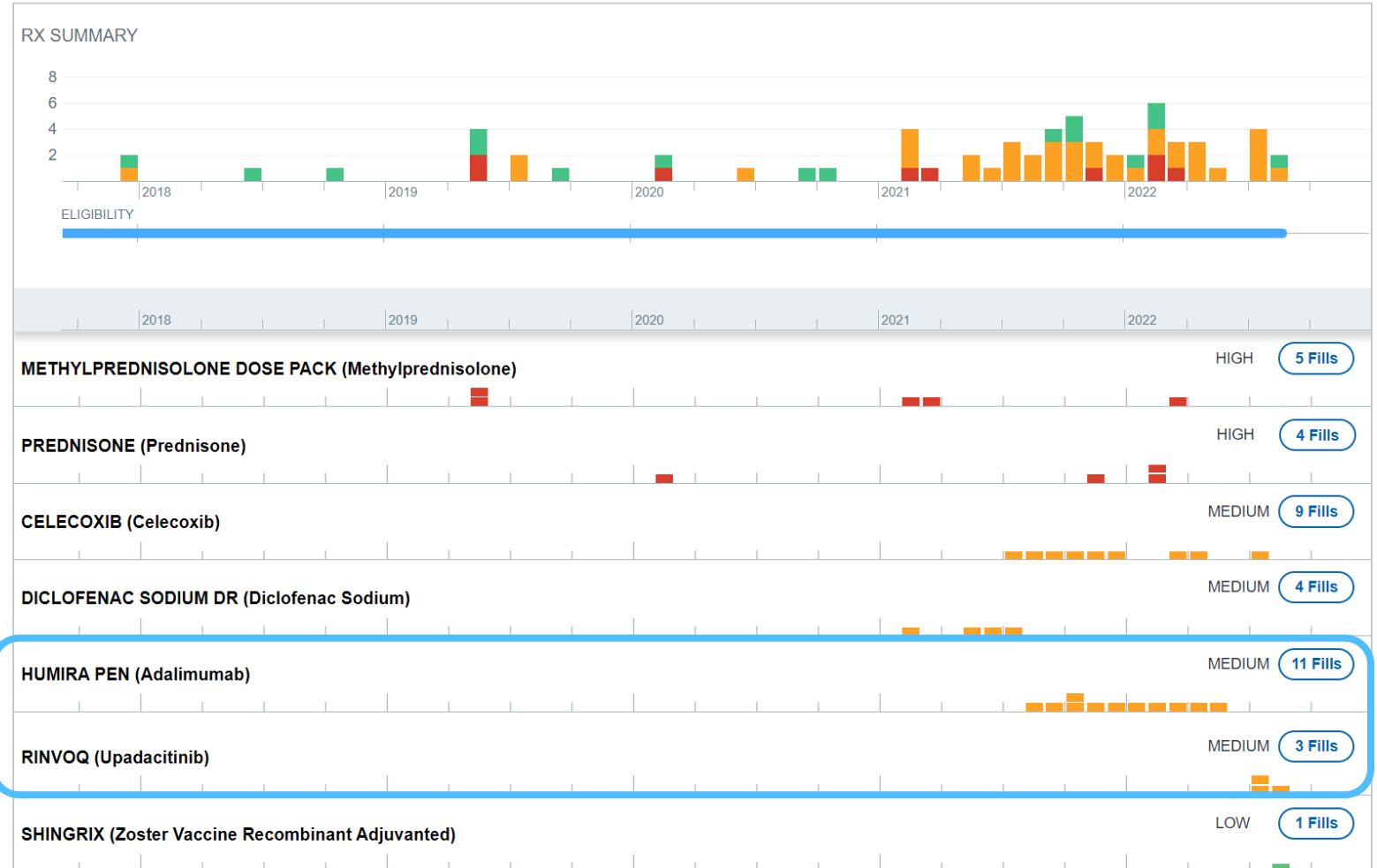
# DIAGNOSIS CODES HELP CLARIFY MULTIUSE MEDICATIONS.

Age: 49 | Gender: F

Application date: 8/2022

Prescription Fills: 66

Medical Codes: 358



# DIAGNOSIS CODES HELP CLARIFY MULTIUSE MEDICATIONS.

Age: 49 | Gender: F

Application date: 8/2022

Prescription Fills: 66

Medical Codes: 358

Ankylosing spondylitis of lumbosacral region

SERVICE DATES	PROVIDER	CLAIM DETAILS
06/14/2022 - 06/14/2022	SUBMITTED PROVIDER [REDACTED] 011 - Office	<b>DIAGNOSIS</b> <b>Ankylosing spondylitis of lumbosacral region</b> ICD-10 M45.7 Other long term (current) drug therapy ICD-10 Z79.899 <b>PROCEDURE</b> Office or other outpatient visit for the evaluation and management of an established patient, usually the presenting problem(s) are of moderate to high severity. Typically 25 minutes are spent face-to-face with the patient and/or family. (Significant, Separately Identifiable E&M Service by the Same Physician on the Same Day of a Procedure or Other Service) CPT-4 99214 C-reactive protein CPT-4 86140 Injection, methylprednisolone acetate, 80 mg HCPCS J1040 Injection, methylprednisolone acetate, 40 mg HCPCS J1030
08/17/2022 - 08/17/2022	SUBMITTED PROVIDER [REDACTED] 011 - Office	<b>DIAGNOSIS</b> <b>Ankylosing spondylitis of lumbosacral region</b> ICD-10 M45.7 Other long term (current) drug therapy ICD-10 Z79.899 <b>PROCEDURE</b> Office or other outpatient visit for the evaluation and management of an established patient, usually the presenting problem(s) are of moderate to high severity. Typically 25 minutes are spent face-to-face with the patient and/or family. CPT-4 99214 C-reactive protein CPT-4 86140

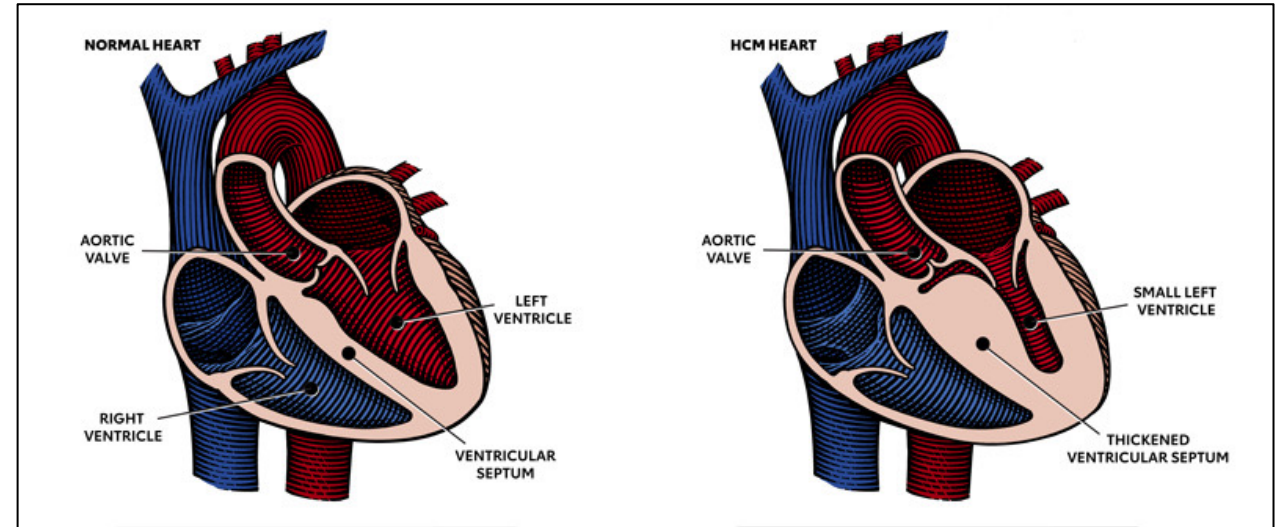


# OTHER

# HCM HAS TRADITIONALLY BEEN AN ELUSIVE CONDITION.

## HYPERTROPHIC CARDIOMYOPATHY (HCM)

- Thickens the heart muscle, which can block blood flow out of the heart
- Risk of arrhythmias, heart failure, sudden cardiac death
- Previous treatment focused on symptoms only:
  - Beta-blockers
  - Verapamil
  - Disopyramide
- Surgery may be required if symptoms persist





# CAMZYOS PROVIDES NEW TREATMENT FOR CARDIOMYOPATHY.

---

## CAMZYOS (mavacamten)

- Administered orally once daily
- Targets the cause of HCM by attaching to heart muscle and promoting a relaxed state
- Camzyos showed significant improvement in exercise capacity and symptoms

Relative mortality

Estimated 180%–220%

# **NEW ALS TREATMENT IS UNLIKELY TO MAKE SIGNIFICANT IMPACT.**

## **RELYVRIO (sodium phenylbutyrate-aurursodiol)**

- Joins riluzole and edaravone as third FDA-approved treatment for ALS
- Efficacy is questionable, and is unlikely to significantly prolong life
- Costs ~\$158,000 per year

**Relative mortality**

Estimated >600%

# **NEW ANTIDEPRESSANT COMBO MAY LEAD TO QUICKER RESULTS.**

## **AUVELITY (dextromethorphan-bupropion)**

- Approved for depression
- Combines cough suppressant with existing antidepressant
- Studies found superior efficacy over bupropion monotherapy
- Likely to be used second-line due to cost

**Relative mortality**

Estimated 140%

# INJECTABLE HIV TREATMENT ALLOWS FOR TWICE YEARLY DOSING.

## SUNLENCA (lenacapavir)

- Injection given twice yearly for multidrug-resistant HIV
  - Account for ~2% of those on HIV treatment
- Unique mechanism of action adds new option in a traditionally deadly disease
- Being studied for HIV pre-exposure prophylaxis (PrEP)

Relative mortality

Estimated >270%

# NEW MEDICATIONS MAY BE PREVALENT BUT REPRESENT LOW RISK.

## **QUVIVIQ (daridorexant)**

- Oral tablet indicated for insomnia
- Same mechanism as Belsomra & Dayvigo
- Likely to be used second-line due to cost

**Relative mortality**

Estimated 130%

## **CIBINQO (abrocitinib)**

- Oral tablet indicated for moderate-severe atopic dermatitis
- Similar mechanism to Olumiant, Xeljanz, and Rinvoq
- Considered later-line therapy

**Relative mortality**

Estimated <100%



# **BIOSIMILAR MEDICATIONS**

2023 – Washington, DC

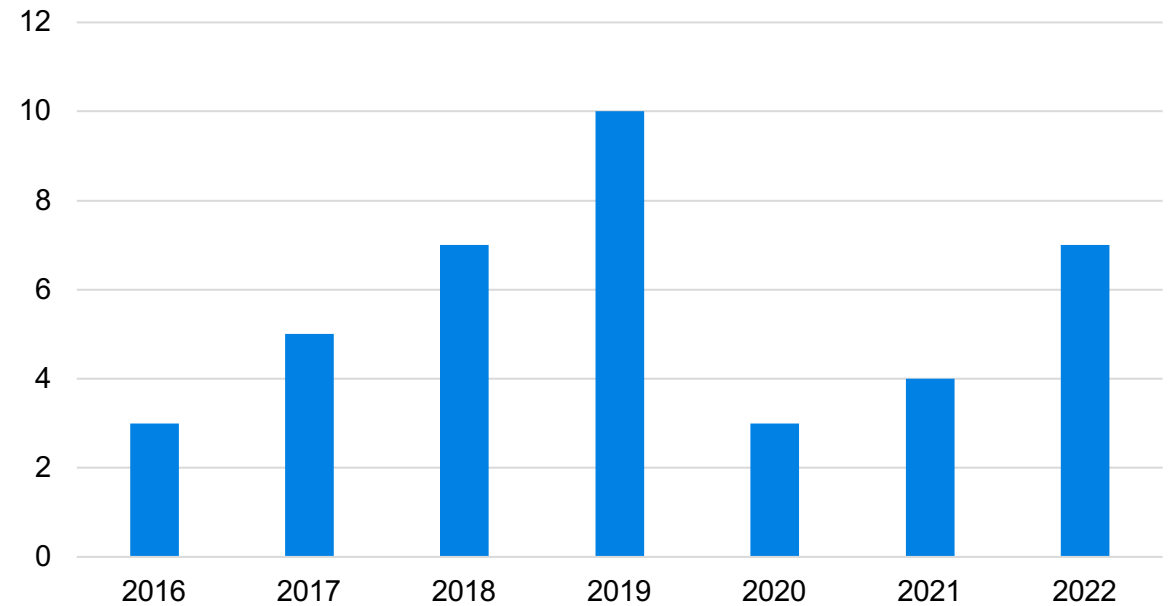
# BIOSIMILAR MEDICATIONS ARE BECOMING MORE COMMON.

## Notable biosimilar approvals

Biosimilar name	Active drug	Reference product
Idacio* Yusimry Hulio Abrilada Hadlima Hyrimoz Cyltezo Amjevita	Adalimumab	Humira
Rezvoglar Semglee	Insulin glargine	Lantus

\*2022 approval

### Biosimilar Medication Approval by Year





# SUMMARY



# **THIRTY-SEVEN NEW MEDICATIONS WERE APPROVED IN 2022.**

**Cancer medications continue to dominate new drug market**

**Advancements in diabetes treatment are finding value in other disease states**

**Treatment of autoimmune conditions continues to evolve**

**Biosimilars are likely to see significant growth in coming years**



# THANK YOU

Matt Glasow, PharmD, MBA  
matt.glasow@milliman.com