
# Clinical Deep Dive:

## What Specialty Pharmacists Actually Do Day-to-Day


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- This presentation is for informational purposes only and does not constitute medical advice.
- All patient-related examples are anonymized and used for illustration only.
- No confidential data is shared, and HIPAA compliance is maintained.
- Please consult qualified professionals before applying any information presented.

# Meet the Presenters

## Emily Eastman PharmD, MBA, CSP

Associate Director | UK Specialty Pharmacy

## Tim McLeroy

Director of Business Development | Noble

# Learning Objectives

1. Describe the role of the specialty pharmacist across the patient journey, including medication access, clinical management, patient education, and longitudinal follow-up.
2. Apply clinical reasoning to specialty pharmacy patient cases by identifying appropriate interventions related to medication safety, monitoring, adherence, and supportive care.
3. Recognize how specialty pharmacists collaborate with interdisciplinary teams to overcome barriers to therapy and improve patient outcomes in complex disease states.

# Specialty or Not?




# What is a Specialty Drug?

Expensive

- >$670/month

Special Handling or Administration Requirements

- Injectable
- IV
- Sterile Preparation

Available through a Limited Network

- Limited Distribution Drug

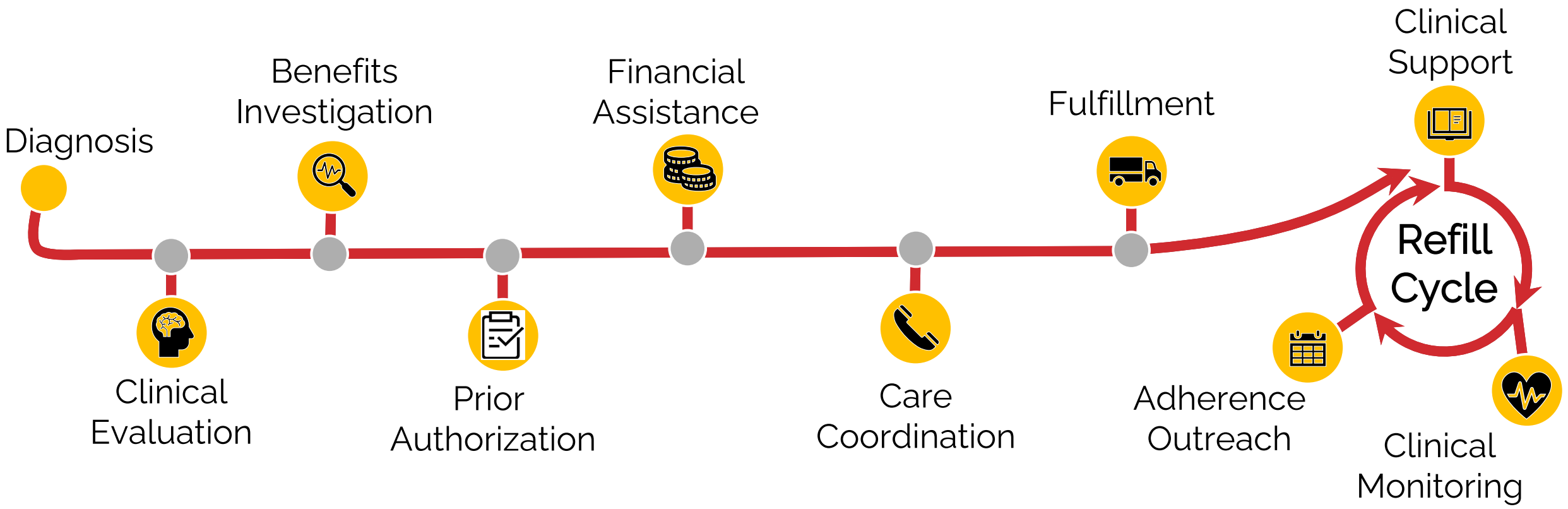
As defined by The Centers of Medicare and Medicaid Services

Treat Complex Conditions

- Cancer, MS, Psoriasis, Ulcerative Colitis, Short Stature….etc.

# What does a Specialty Pharmacy do?


# The Patient Journey

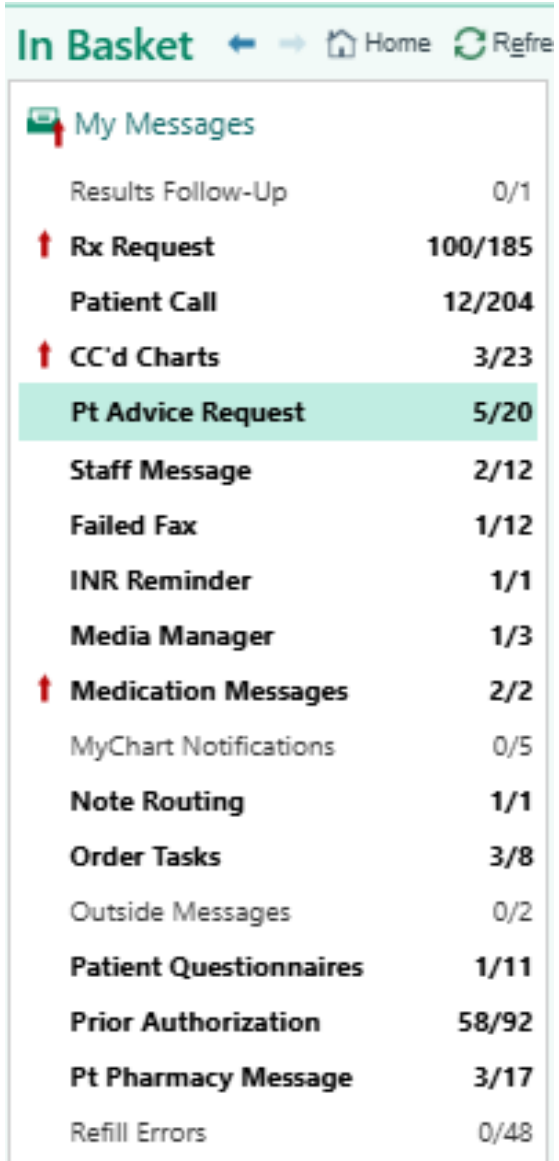


# Diagnosis and Clinical Evaluation

- Patient referred to specialty clinic
  - Often the result of acute worsening of symptoms.
- Seen by provider to determine course of therapy
  - Clinics may have embedded pharmacists.
  - RPh will work with providers to evaluate best therapy choices.

# Welcome to Your First Day!

- You are a pharmacist in clinic.
- You start your day at 8:00AM and see your messages.
- MD comes into your pod and says Ms. N. Aspen is in Room 4 – I want her to start **Ofatumumab**.
- What do you do first?



# Choose Your Own Adventure

## Go into Room 4 and talk to Ms. N Aspen

- Determine Appropriateness
- Patient Counseling
- Device Training

## Send Prescription to Specialty Pharmacy

- Benefit Investigation
- Prior Authorization
- Financial Assistance
- Care Coordination
- Fulfillment

# Is Kesimpta appropriate for N. Aspen?

- Indication:
  - SUBQ: Initial: 20 mg once weekly for 3 doses (weeks 0, 1, and 2); maintenance: 20 mg once monthly starting at week 4.
- Warnings/Precautions:
  - Vaccination History
  - Lab Review:
    - Liver Function Tests
    - Immunoglobulins
  - Active Infections
    - Hepatitis B
    - Tuberculosis

# They all perform the same job, but they all are not the same…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# Patient Counseling and Device Training

- **Training Gaps** – *49% of patients* are never trained
- **Recall Erosion** between dosing – *90% of learned information* is forgotten in a week
- **Improper use** – *84% of patients* do not use autoinjectors correctly
- **Negative Transfer** – Past device experience can interfere when switching treatments or devices

1. Lang, V.A. Nalan, D. (2018). Combination Product Patient Training: How are Patients Trained and Who Conducts the Training? *The American Society of Mechanical Engineers. Frontiers in Biomedical Devices, 2018 Design of Medical Devices conference ():* V001T09A003. Retrieved from http://proceedings.asmedigitalcollection.asme.org/proceeding.aspx?articleid=2685407 2. Potera, Carol. (2015). Misuse of Autoinjectors and Inhalers. *American Journal of Nursing, 115 (3),* pp.17. Retrieved from https://journals.lww.com/ajnonline/Fulltext/2015/03000/Misuse_of_Autoinjectors_and_Inhalers.12.aspx 3. Kohn, Art. (2014). Brain Science: The forgetting Curve-the Dirty Secret of Corporate Training. *Learning Solutions.* Retrieved from: https://www.learningsolutionsmag.com/articles/1379/brain-science-the-forgetting-curvethe-dirty-secret-of-corporate-training

# Prescription Sent to SP Pharmacy

- Review patient's pharmacy and/or medical benefits
  - Insurance Plans:
    - Commercial
    - Medicaid
    - Medicare
    - Military

- Projected Patient Costs:
  - Deductible
    - Amount paid by policy holder prior to insurance paying <u>any</u> covered expenses
  - Out of Pocket
    - Amount paid by policy holder prior to insurance paying <u>all</u> covered expenses

Adobe Stock Image, Free

# ABCs of Medicare

## Part A: Hospital

- Free if you have worked and paid into Social Security taxes for at least 10 years
- Coverage includes:
  - Inpatient hospital stays
  - Care in skilled nursing facilities
  - Hospice care
  - Some home health care

## Part B: Medical

- Optional Enrollment and has a monthly premium for coverage
- Coverage includes:
  - Preventative services:
    - Vaccines- Flu, Pneumococcal, & some Hepatitis B
  - Durable medical equipment
  - Diabetic testing supplies
  - Limited outpatient prescription drugs
    - Oral Anticancer Drugs
    - Nebulizer Medication
    - Immunosuppressive Drugs

# And the rest of the alphabet...

## Part C: Advantage Plan

- Private companies contract with Medicare to cover beneficiaries' Medicare benefits.
- Coverage includes:
  - All services offered through Part A & Part B Medicare
  - Most have built-in prescription plans
- Advantage = Extras + lower premiums
- Disadvantage = Not eligible for Supplemental Plans

## Part D: Prescription Drug

- Administered by an insurance company or other private company that has been approved by Medicare.
- Enrollment is optional and most plans have monthly premiums as well as yearly deductibles, coinsurance, and/or copayments.

## Medicare Supplemental Plans (MediGap)

- A-D, F, G, K-N
- Helps to supplement health care costs that Original Medicare doesn't cover (A or B).
- These gaps include copayments, coinsurance, and deductibles.
- Does NOT cover Medicare Part D copays.

# Which card do you use?




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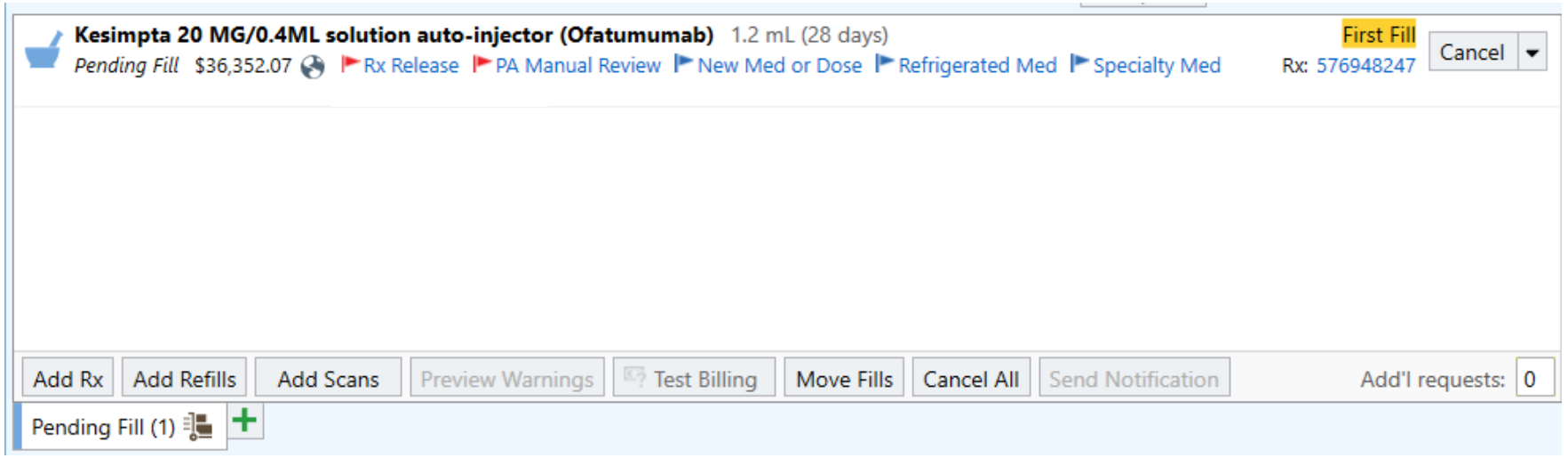
# The Claim Rejects




- Review prior authorization criteria per payer and start pharmacy prior authorization.
  - Diagnosis Code (ICD10)
  - Tried and failed therapy
  - Labs/Imaging


Is this a request for brand or generic?

☐ Brand ☐ Generic

1. What is the patient's diagnosis?

- ☐ Active secondary progressive multiple sclerosis
- ☐ Clinically isolating syndrome
- ☐ Relapsing-remitting multiple sclerosis
- ☐ Relapsing multiple sclerosis
- ☐ Other diagnosis

**Assessment:**

Relapsing-Remitting Multiple Sclerosis


| Baseline Labs | Result |
|---|---|
| HBsAg | Negative |
| Total anti-HBc | Negative |
| Anti-HBs | Positive = Immune |
| Hepatitis C Ab | Negative |
| HIV Ag/Ab | Nonreactive |
| QuantiFERON-TB Gold | Negative |
| CBC with differential | WNL |
| IgG / IgM / IgA | WNL |

2. Does the patient have any active infections?

☐ Yes ☐ No

3. Will the patient be given live vaccines or live-attenuated vaccines while on Kesimpta?

☐ Yes ☐ No

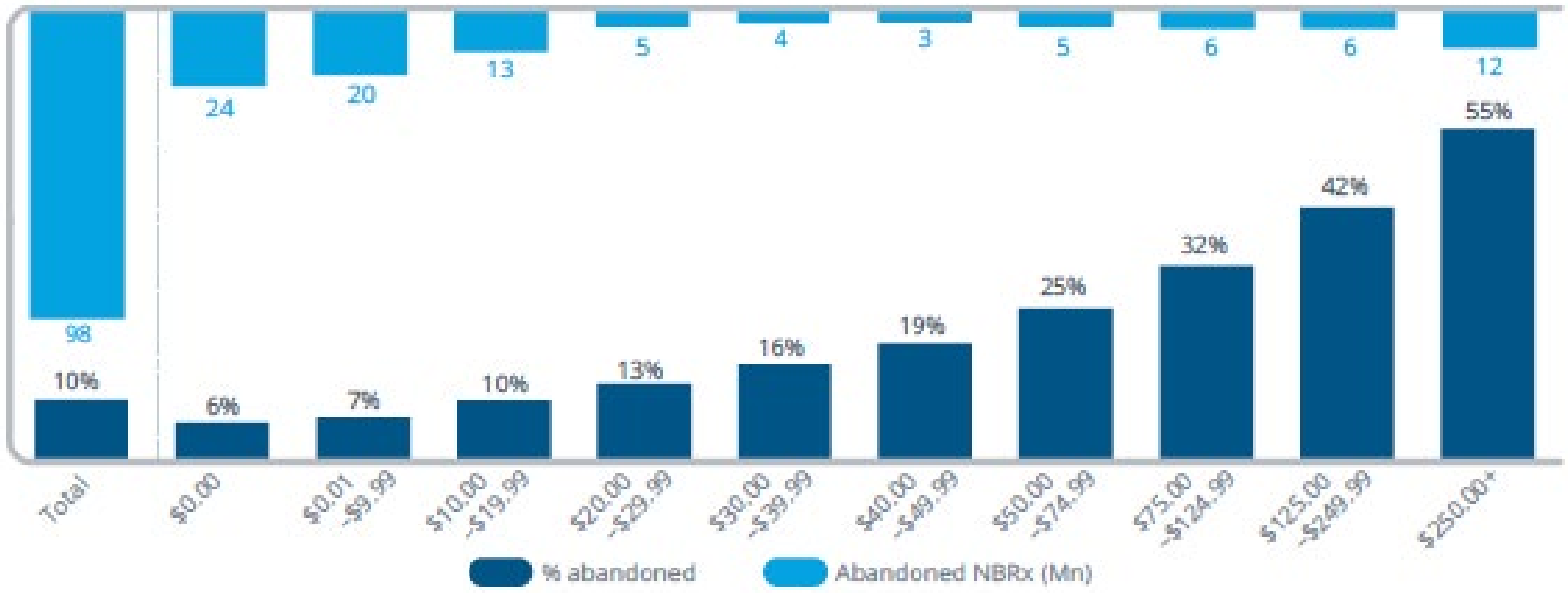
# PA approved! But....it's $2,300....


| | |
|---|---|
| Copay Card | Provided by pharmaceutical manufacturers to help patients reduce the copay; typically covers all or part of the patient's out-of-pocket copayment for a medication; usually only for brand name products |
| Grant | Lump sum monetary 'award' provided by government agencies, nonprofit organizations, or foundations that can be used for copayments for specific health conditions |
| Manufacturer Assistance Program | Offered by pharmaceutical companies to provide medications at no cost to eligible patients; typically used for people who are uninsured or underinsured |
| Coupon Card | Offered by third party companies; may not be combined with insurance; displays the 'discount' prices to customers at pharmacy |
| Free Trial Offer | Provided by pharmaceutical manufacturers to supply a one-time medication supply, generally 30-day, to patients free of charge; may not be combined with insurance |

# Why does Financial Assistance matter?

## Patients starting new therapy abandoned 98Mn prescriptions at pharmacies in 2023 with increasing frequency as costs rise

**Exhibit 26: 14-day abandonment share of new-to-product prescriptions by final out-of-pocket cost in 2023, all payers, all products**




Source: IQVIA National Prescription Audit: New to Brand, LAAD Sample Claims Data, Dec 2023; IQVIA Institute, Mar 2024.

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# What Financial Assistance Option do you use?

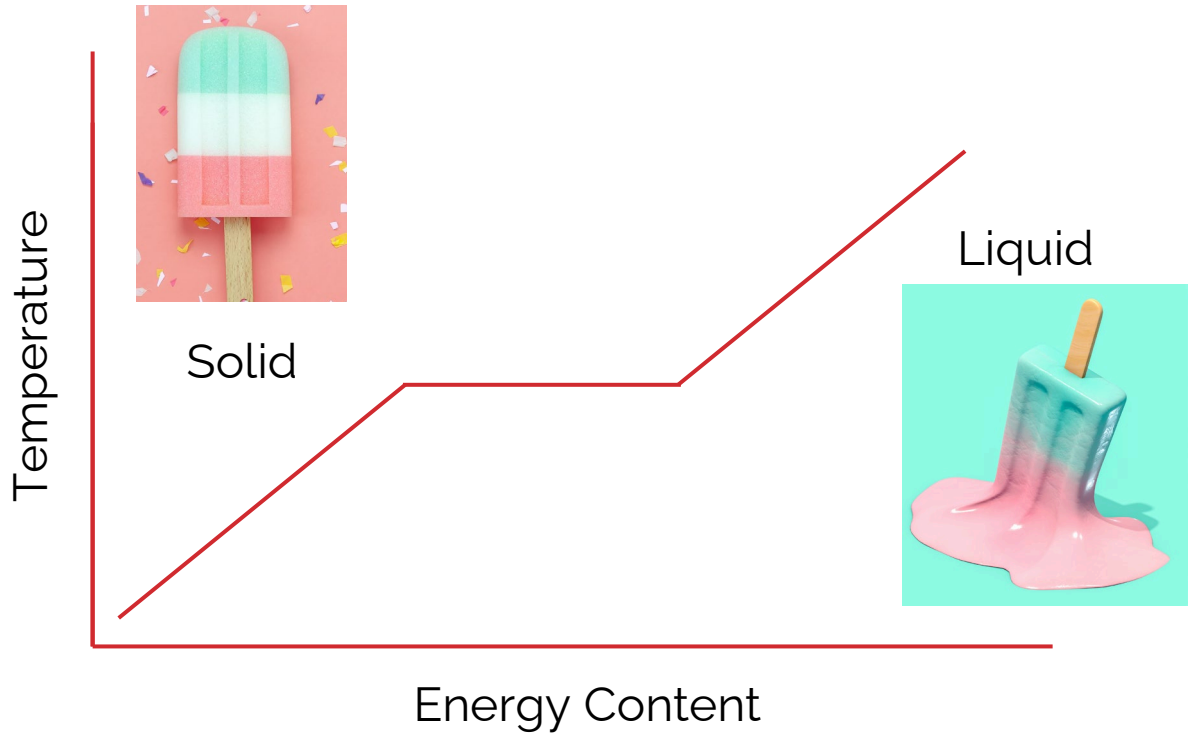
| | Commercial | Medicare | Medicaid | Uninsured |
|---|---|---|---|---|
| Copay Card | ✓ | ✗ | ✗ | 🔍 |
| Grant | ✓ | ✓ | ✓ | 🔍 |
| Manufacturer Assistance Program | 🔍 | 🔍 | ✓ | ✓ |
| Discount Card | ✓ | ✓ | ✓ | ✓ |
| Free Trial | ✓ | ✓ | ✓ | ✓ |

# Care Coordination

- Pharmacist calls a patient to discuss:
  - Care Plan
  - Education
  - Coordination of care and next steps
  - Barriers to care or patient questions

# Fulfillment

- Most specialty medications are shipped to the patient homes
  - Cold Chain Process
  - Payor restrictions
- Infusion patients
  - Labs
  - Appointments




# Clinical Monitoring and Support

- Specialty disease states often chronic and many are terminal
- Medications associated with many adverse drug events
- Pharmacists available for any issues which may arise
- Pharmacists perform clinical interventions
  - Provide management strategies
  - Alert provider
  - Connect patient to care

# Adherence Outreach

- Pharmacy technicians perform proactive refill management
  - Phone calls
  - EHR applications
- Synchronization of medications
- Outreaches often identify other needs
  - Barriers
  - Side effects

# Discovery of Barriers

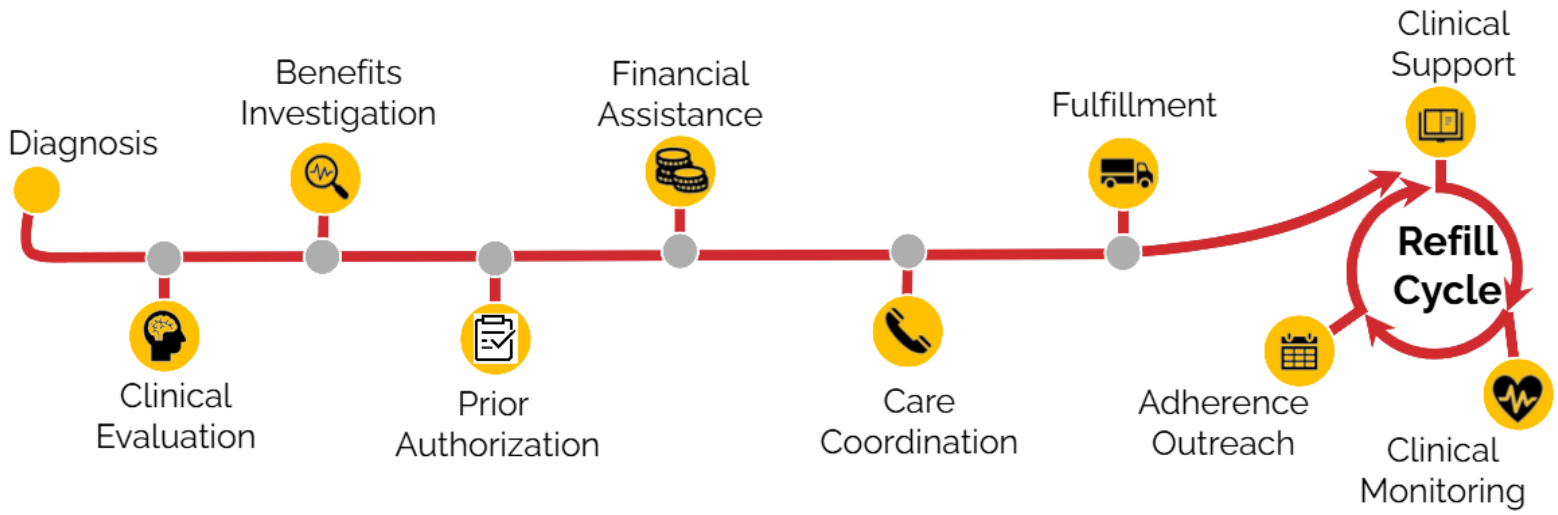
Ms. Aspen reports injection site reactions and that she just had follow up labs. You look up the lab results in the EHR:

| Hepatic Function Panel | Result | Reference Range |
|---|---|---|
| AST | 648 U/L | 10–40 U/L |
| ALT | 812 U/L | 7–56 U/L |
| Alkaline Phosphatase | 186 U/L | 40–129 U/L |
| Total Bilirubin | 1.8 mg/dL | 0.2–1.2 mg/dL |
| Direct Bilirubin | 0.9 mg/dL | 0.0–0.3 mg/dL |
| Albumin | 4.1 g/dL | 3.5–5.0 g/dL |

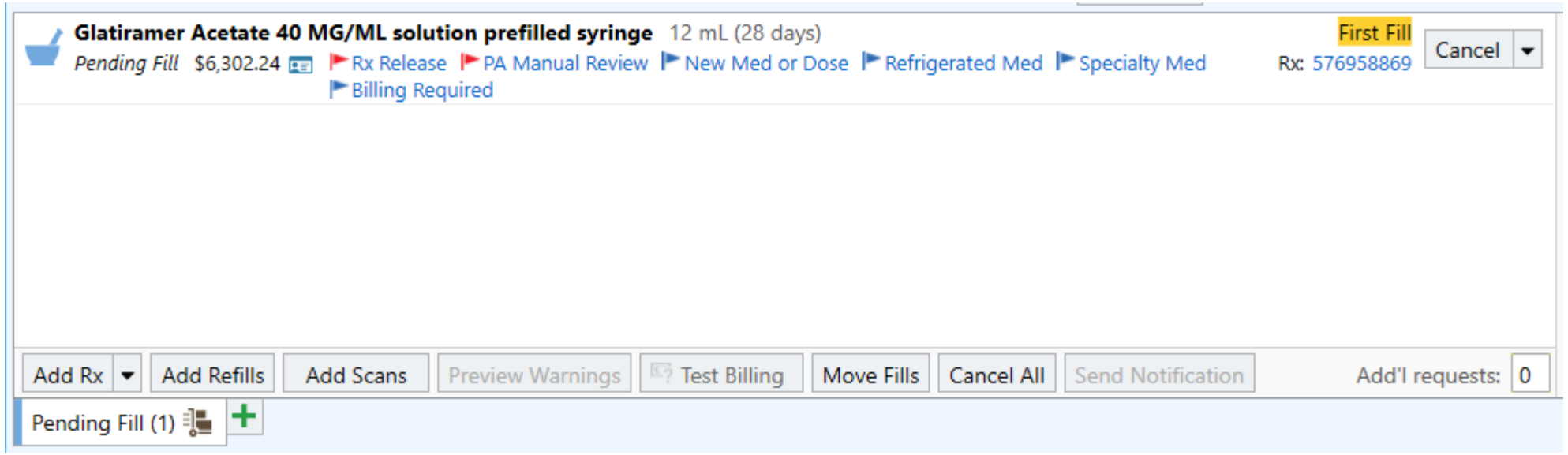
- *What are your next steps?*

# Consult with the MD

- It is determined that Kesimpta is clinically inappropriate to continue.
- Ms. Aspen is prescribed glatiramer acetate.
- What are your next steps?



# The Claim Rejects...again...

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Is this a request for brand or generic?

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1. What is the patient's diagnosis?

☐ Relapsing-remitting multiple sclerosis
☐ Relapsing multiple sclerosis
☐ Other diagnosis

2. Is the medication prescribed by or in consultation with a neurologist?

☐ Yes ☐ No

3. Previous disease modifying treatment:_____

# PRIOR AUTHORIZATION DENIED

**Patient:**
**Natalie Aspen**

**Diagnosis:**
Relapsing-Remitting
Multiple Sclerosis (RRMS)

**Medication Requested:**
**Glatiramer acetate 40 mg/mL syringe**
Inject 40 mg subcutaneously
three times weekly

**Date of Request:**
September 21, 2026

## DENIAL REASON:

The requested medication is not on the plan's formulary.
The preferred product is **Glatopa®** (glatiramer acetate injection).

## NEXT STEPS:

- Provider may submit a new prescription for the preferred product.
- If clinical justification is available for the requested product, an appeal may be submitted.

**Plan Preferred Product:**
**GLATOPA®**
(glatiramer acetate injection)
40 mg/mL


What now?


# What do you do next?

A. Appeal for generic glatiramer acetate?

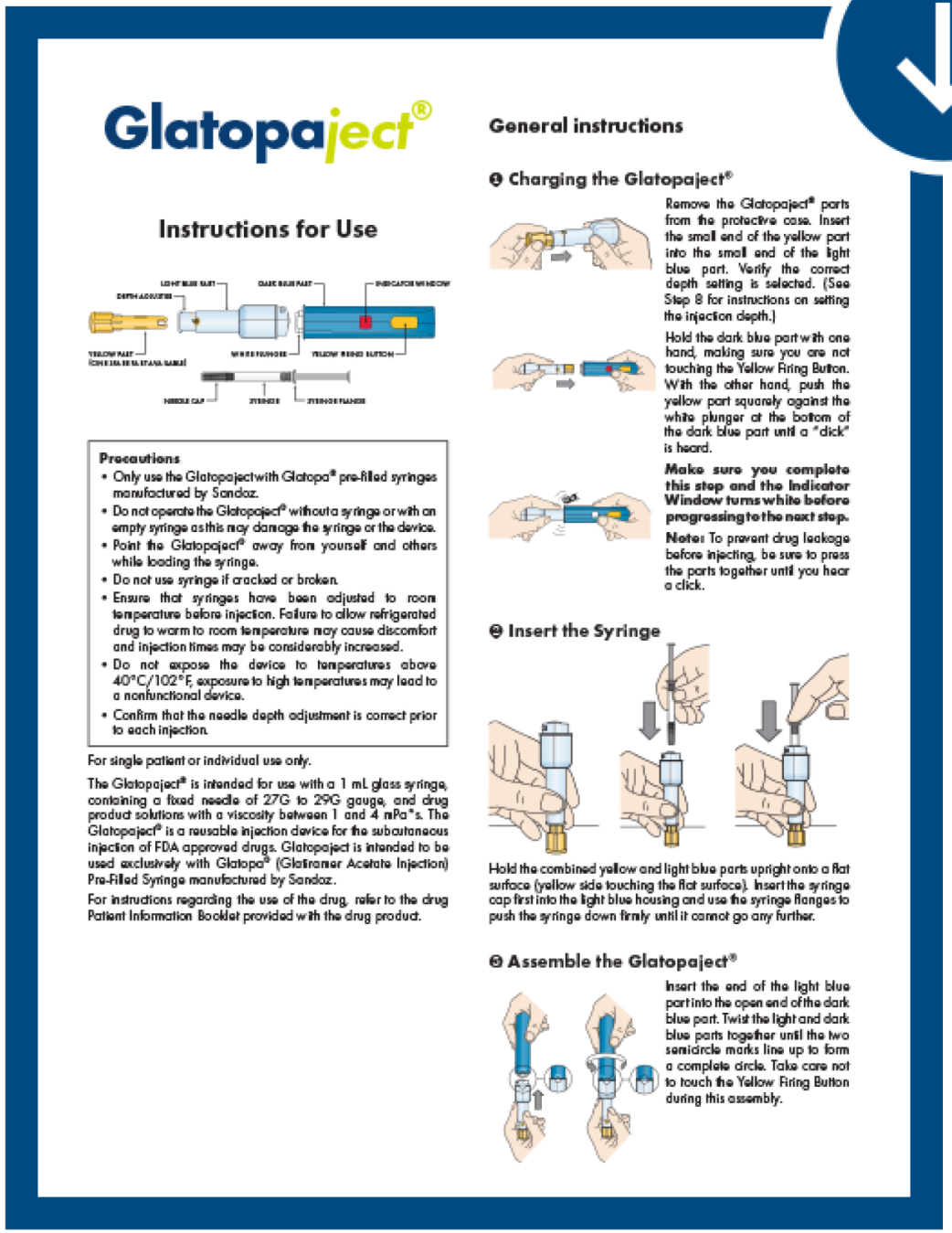
B. Contact the prescriber for a new prescription for the preferred product

C. Switch back to Kesimpta

D. Tell Natalie insurance will not cover treatment

# Care Coordination

- Pharmacist **calls** a patient to discuss:
  - Care Plan
  - Education
    - How do you counsel a patient on injections over a phone?
    - How does the patient (and you) leave the conversation feeling confident?
  - Coordination of care and next steps
  - Barriers to care or patient questions



Glatopaject®

## Instructions for Use



**Precautions**

- Only use the Glatopaject with Glatopa® pre-filled syringes manufactured by Sandoz.
- Do not operate the Glatopaject® without a syringe or with an empty syringe as this may damage the syringe or the device.
- Point the Glatopaject® away from yourself and others while loading the syringe.
- Do not use syringe if cracked or broken.
- Ensure that syringes have been adjusted to room temperature before injection. Failure to allow refrigerated drug to warm to room temperature may cause discomfort and injection times may be considerably increased.
- Do not expose the device to temperatures above 40°C/102°F, exposure to high temperatures may lead to a nonfunctional device.
- Confirm that the needle depth adjustment is correct prior to each injection.

For single patient or individual use only.

The Glatopaject® is intended for use with a 1 mL glass syringe, containing a fixed needle of 27G to 29G gauge, and drug product solutions with a viscosity between 1 and 4 mPa*s. The Glatopaject® is a reusable injection device for the subcutaneous injection of FDA approved drugs. Glatopaject is intended to be used exclusively with Glatopa® (Glatiramer Acetate Injection) Pre-Filled Syringe manufactured by Sandoz.

For instructions regarding the use of the drug, refer to the drug Patient Information Booklet provided with the drug product.

### General instructions

**❶ Charging the Glatopaject®**



Remove the Glatopaject® parts from the protective case. Insert the small end of the yellow part into the small end of the light blue part. Verify the correct depth setting is selected. (See Step 8 for instructions on setting the injection depth.)



Hold the dark blue part with one hand, making sure you are not touching the Yellow Firing Button. With the other hand, push the yellow part squarely against the white plunger at the bottom of the dark blue part until a "click" is heard.



**Make sure you complete this step and the Indicator Window turns white before progressing to the next step.**

**Note:** To prevent drug leakage before injecting, be sure to press the parts together until you hear a click.

**❷ Insert the Syringe**

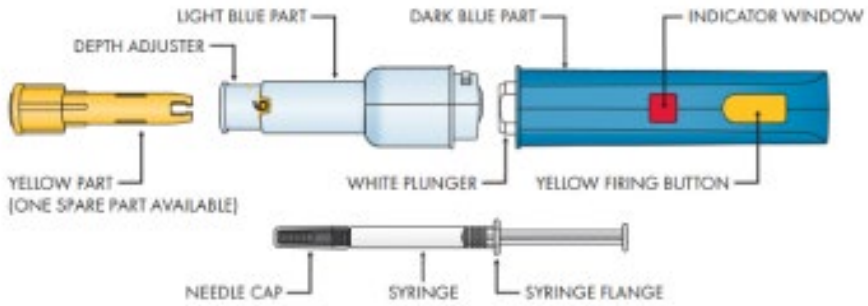


Hold the combined yellow and light blue parts upright onto a flat surface (yellow side touching the flat surface). Insert the syringe cap first into the light blue housing and use the syringe flanges to push the syringe down firmly until it cannot go any further.

**❸ Assemble the Glatopaject®**



Insert the end of the light blue part into the open end of the dark blue part. Twist the light and dark blue parts together until the two semicircle marks line up to form a complete circle. Take care not to touch the Yellow Firing Button during this assembly.




## Many manufacturers offer:

- Nurse services
  - Injection training
- Tester devices
- Online videos

# Summary

- Specialty pharmacy is everything that happens between “prescribe” and “patient successfully starts therapy”.

- The specialty pharmacist connects every step:
  - Clinical Appropriateness > Access > Education > Confidence > Treatment > Repeat PRN

- Every barrier is an opportunity for the specialty pharmacist to intervene and keep the patient moving toward therapy.


# Thank You

Add website/contact information here