

# IBD

APP & NURSE  
PRECEPTORSHIP

## Managing Access Issues in IBD



# IBD in the Real World: Meet JT

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## History of Present Illness

- 25-year-old man diagnosed with UC 2 years ago
  - Initially treated with mesalamine and prednisone
- He experiences a flare 1 year later
  - Treated with a second round of prednisone, but is having intolerable adverse effects
  - Currently having 5 BMs per day, almost all of which are bloody
  - Colonoscopy confirms moderately severe colitis, with continuous, symmetric involvement from the anal verge to 50 cm
- Adalimumab monotherapy induction and maintenance therapy started



# IBD in the Real World: Meet JT

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## History of Present Illness

- At follow-up 2 months later, JT reports 8 BMs per day, with occasional blood in stools, urgency, nocturnal awakenings to defecate, and oral ulcers



# IBD in the Real World: Meet JT

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**How would you manage this patient?**

# IBD in the Real World: Meet JT

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- Vedolizumab induction therapy is ordered
- Request for prior authorization submitted



# IBD in the Real World: Meet JT



**Medical Claim Form**

This form can be used with all medical plans.  
We've added instructions on the back of this form to make it easy for you to complete.

**PRIMARY CUSTOMER INFORMATION: Primary Customer complete this section**

A1. PRIMARY CUSTOMER'S NAME (Last, First, Middle) **Williams Lynne**

B1. DATE OF BIRTH **MM/DD/YYYY**

C. PRIMARY CUSTOMER'S MAILING ADDRESS ( incl. Street) **5679 Random Street**

D. NUMBER OF PRIMARY CUSTOMER SOCIAL SECURITY NUMBER (E. ACCOUNT NO. on the front of your Card ID card)

F. EMPLOYER NAME

G. PRIMARY CUSTOMER STATUS: ☒ EMPLOYED ☐ RETIRED ☐ DISABLED

H. EFFECTIVE DATE

**PATIENT INFORMATION: Complete this section only if the patient is not the primary customer**

A. PATIENT'S NAME (Last, First, Middle)

B. RELATIONSHIP TO PRIMARY CUSTOMER: ☐ Spouse ☐ Child ☐ Other

C. DATE OF BIRTH **MM/DD/YYYY**

D. GENDER ☐ M ☐ F

E. PATIENT'S ADDRESS, IF DIFFERENT FROM CUSTOMER ADDRESS

F. AT THE TIME MEDICAL SERVICE WAS PROVIDED WAS THE PATIENT: ☐ EMPLOYED FULL TIME ☐ STUDENT FULL TIME ☐ N/A

**COMPLETE THIS SECTION ONLY IF YOU ARE MAKING AN OCCUPATIONAL CLAIM INFORMATION: Complete this section only if you are making an occupational (work-related) illness or injury claim because of an accident or occupational illness or injury**

A. DATE OF ACCIDENT OR INJURY **MM/DD/YYYY**

B. HOW ACCIDENT OR INJURY OCCURRED

C. DATE OF ACCIDENT OR BEGINNING OF ILLNESS **MM/DD/YYYY**

D. DATE OF ACCIDENT OR BEGINNING OF ILLNESS **MM/DD/YYYY**

E. ARE YOU OR YOUR DEPENDENT COVERED BY ANOTHER INSURANCE PLAN? ☐ YES ☐ NO

F. DATE OF PLAN (FROM OR BEFORE ACCIDENT OR INJURY)

**FAMILY/OTHER INFORMATION: Complete only if claim is for a dependent and coverage is in effect**

A. SPOUSE EMPLOYED? ☐ YES ☐ NO

B. NAME OF SPOUSE (Last, First, Middle) **Williams Lynne**

C. NAME OF SPOUSE'S EMPLOYER

D. DATE OF PLAN (FROM OR BEFORE ACCIDENT OR INJURY)

E. IS THE PATIENT COVERED UNDER ANOTHER HEALTH INSURANCE PLAN? ☐ YES ☐ NO

F. DATE OF PLAN (FROM OR BEFORE ACCIDENT OR INJURY)

G. IS THE PATIENT COVERED UNDER MEDICAID? ☐ YES ☐ NO

**CERTIFICATION**

Any person who knowingly and with intent to defraud any insurance company or other person, provides false information concerning any statement of claim containing any materially false information; or (2) conceals for the purpose of obtaining a benefit under this policy, any material fact therein, commits a fraudulent insurance act which is a crime. For residents in the following states, please see the last page of this form: Alaska, Arizona, California, Colorado, District of Columbia, Florida, Kentucky, Maryland, Minnesota, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas and Virginia.

I certify that the information supplied is true and correct.

DATE **MM/DD/YYYY**

**PRIMARY CUSTOMER'S SIGNATURE**  
**X Lynne Williams**

**PAYMENT INSTRUCTIONS**

I authorize **X Lynne Williams** to make payment directly to the health care professional listed on the enclosed bills.

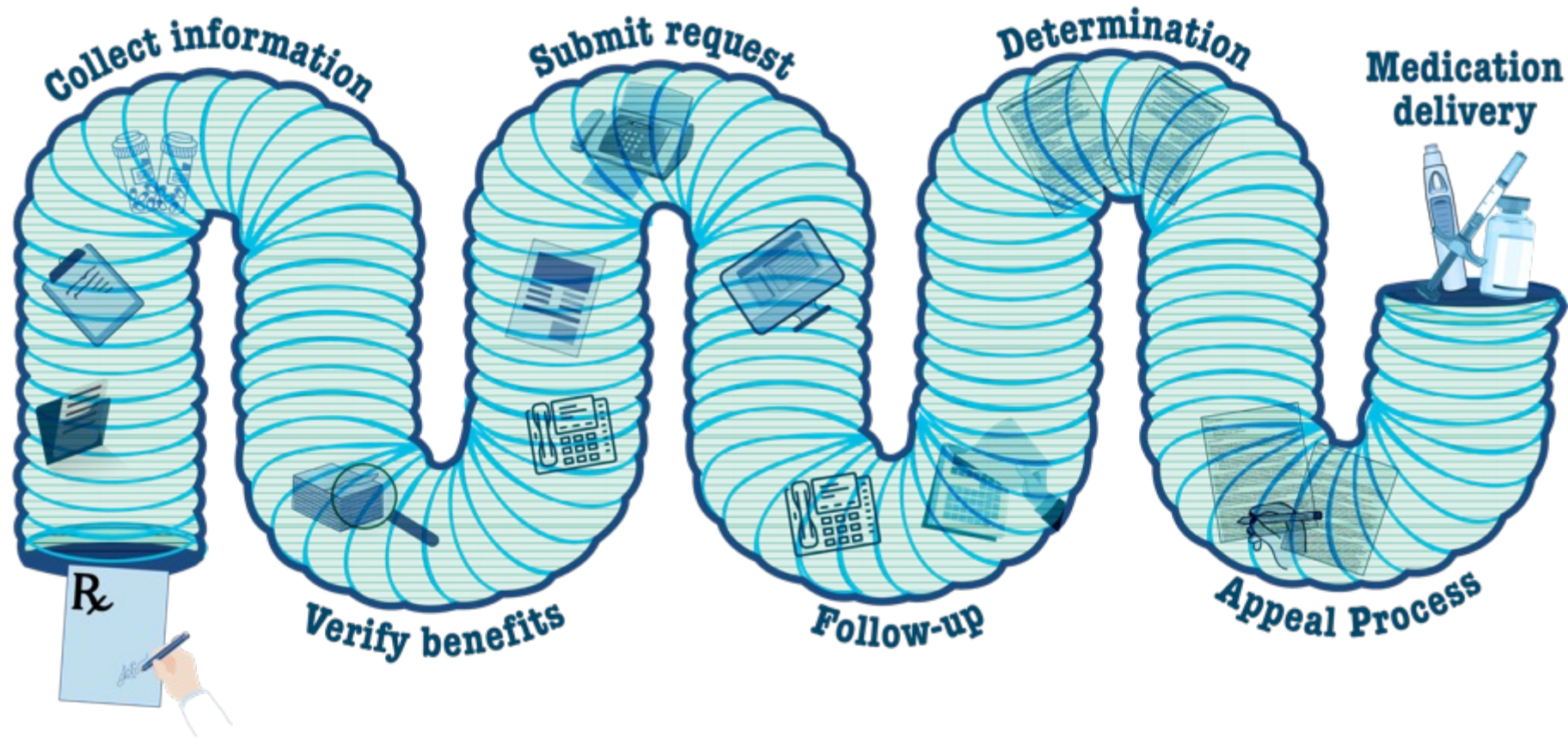
DATE **MM/DD/YYYY**

**IMPORTANT:** When the health care professional holds a contract, we will always pay the health care professional directly, even if this section is left unsigned. We pay the health care professional at the contracted rate. If you already paid the health care professional for the services you received, you should ask your health care professional to pay you back.

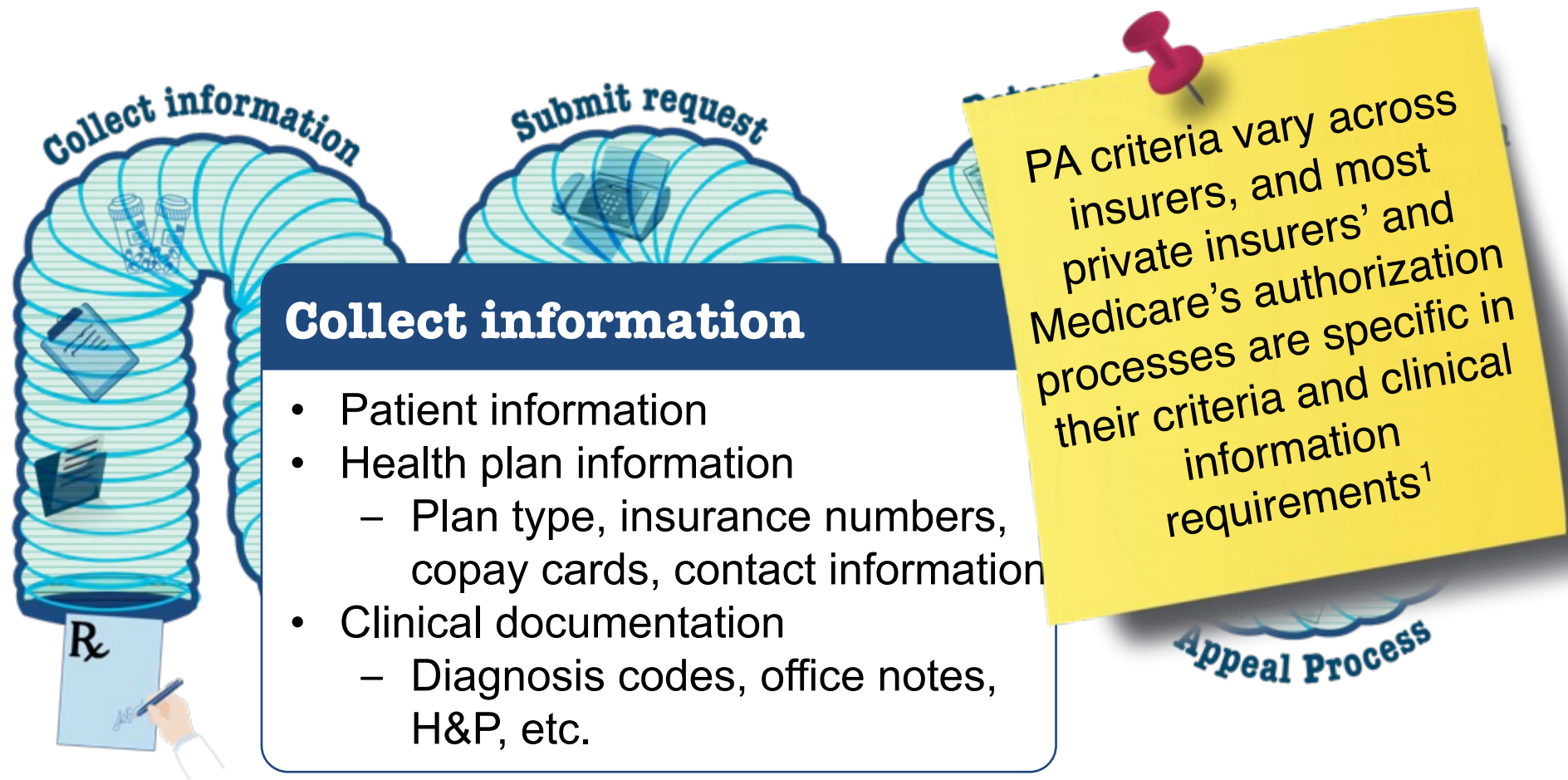
**NOTE:** We may disclose the information on this form to other persons and entities, including your employer (if your coverage is through your employer). We may do this to process the claim or administer the health plan.

Vedolizumab induction therapy is ordered and request for prior authorization submitted

# The prior authorization process

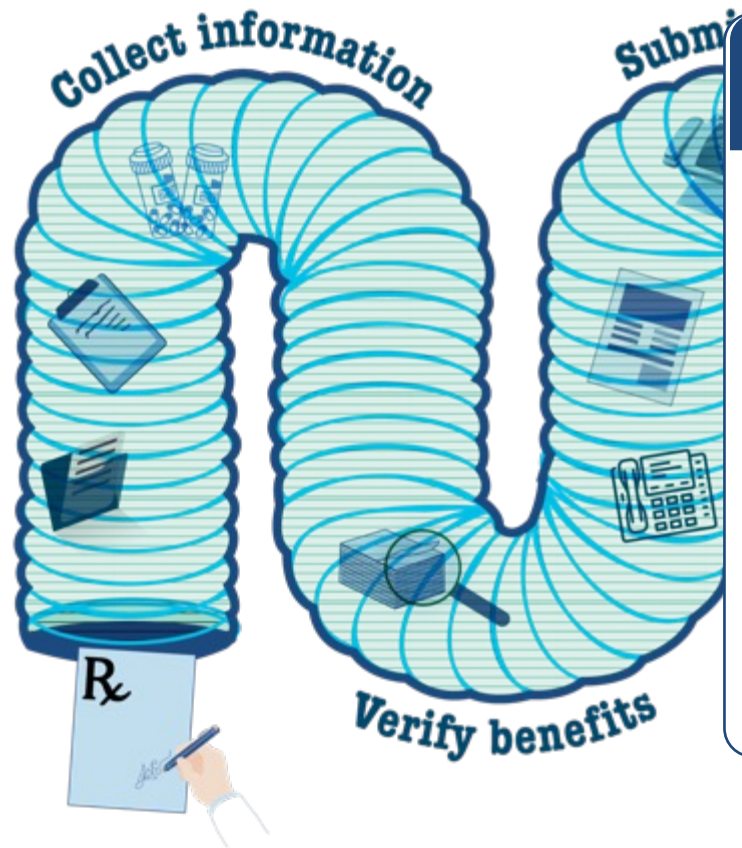


# The prior authorization process: collecting information





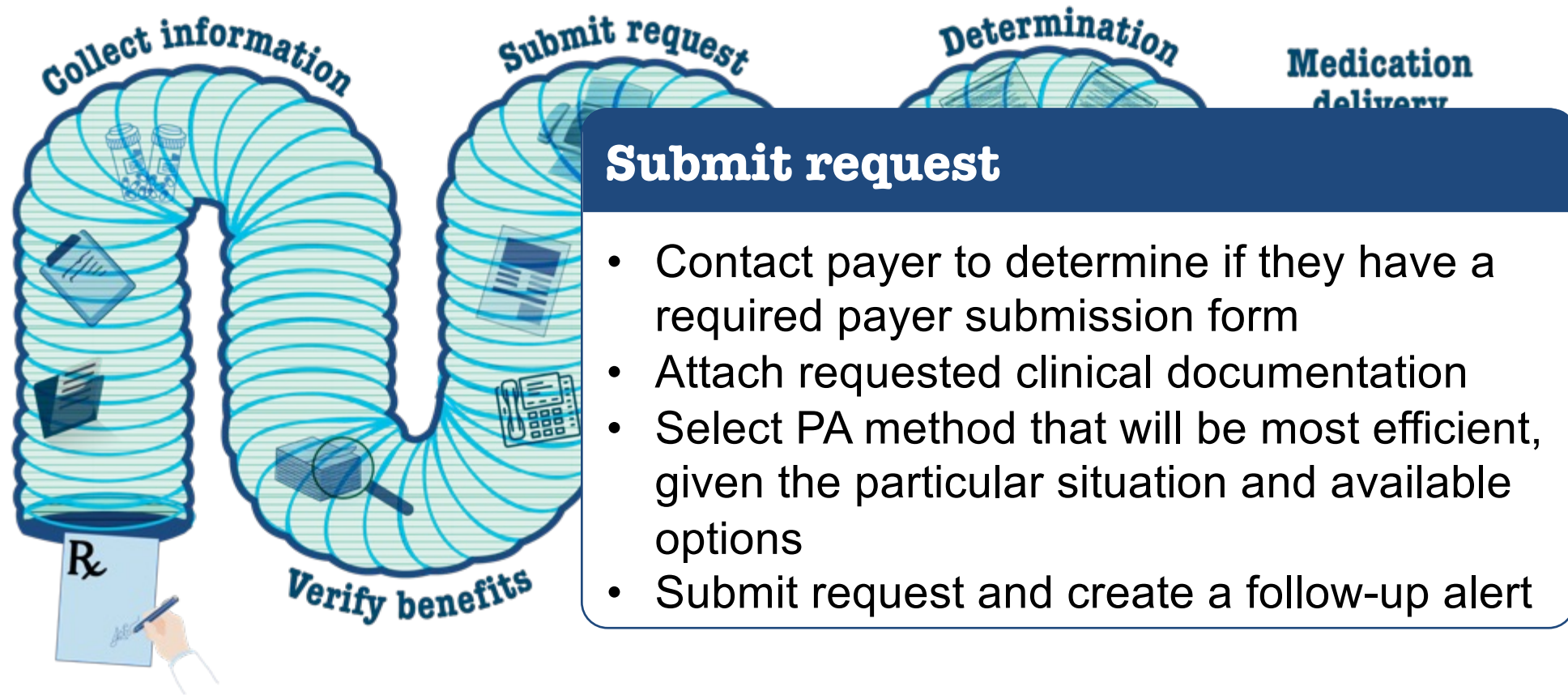
# The prior authorization process: verifying benefits



## Verify benefits

- Contact payer
- Verify benefits and patient out-of-pocket cost (eg, co-pay, deductible, out-of-pocket maximum)
- Verify eligibility and medical policy requirements
- Verify physician and facility contract network status with health plan
- Verify payer requirements for PA

# The prior authorization process



# PA Submission

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**Fax**



**Secure E-Mail**



**Electronic  
transactions (EHR)**



**Phone**



**Payer Portal**

EHR, electronic health record.

American Medical Association. Prior Authorization Toolkit. Available at <https://www.ama-assn.org/practice-management/addressing-prior-authorization-issues>. Accessed June 28, 2021.

# Resources to facilitate approval and optimal clinical use of biologics in IBD

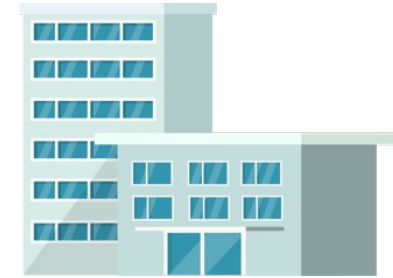


## Pharmaceutical manufacturers

Template letters of medical necessity  
Medical science liaisons (MSLs)



## Specialty pharmacies



## Insurance companies

Coordinators/advocates  
Pharmacies



## Crohn's & Colitis Foundation (CCF)

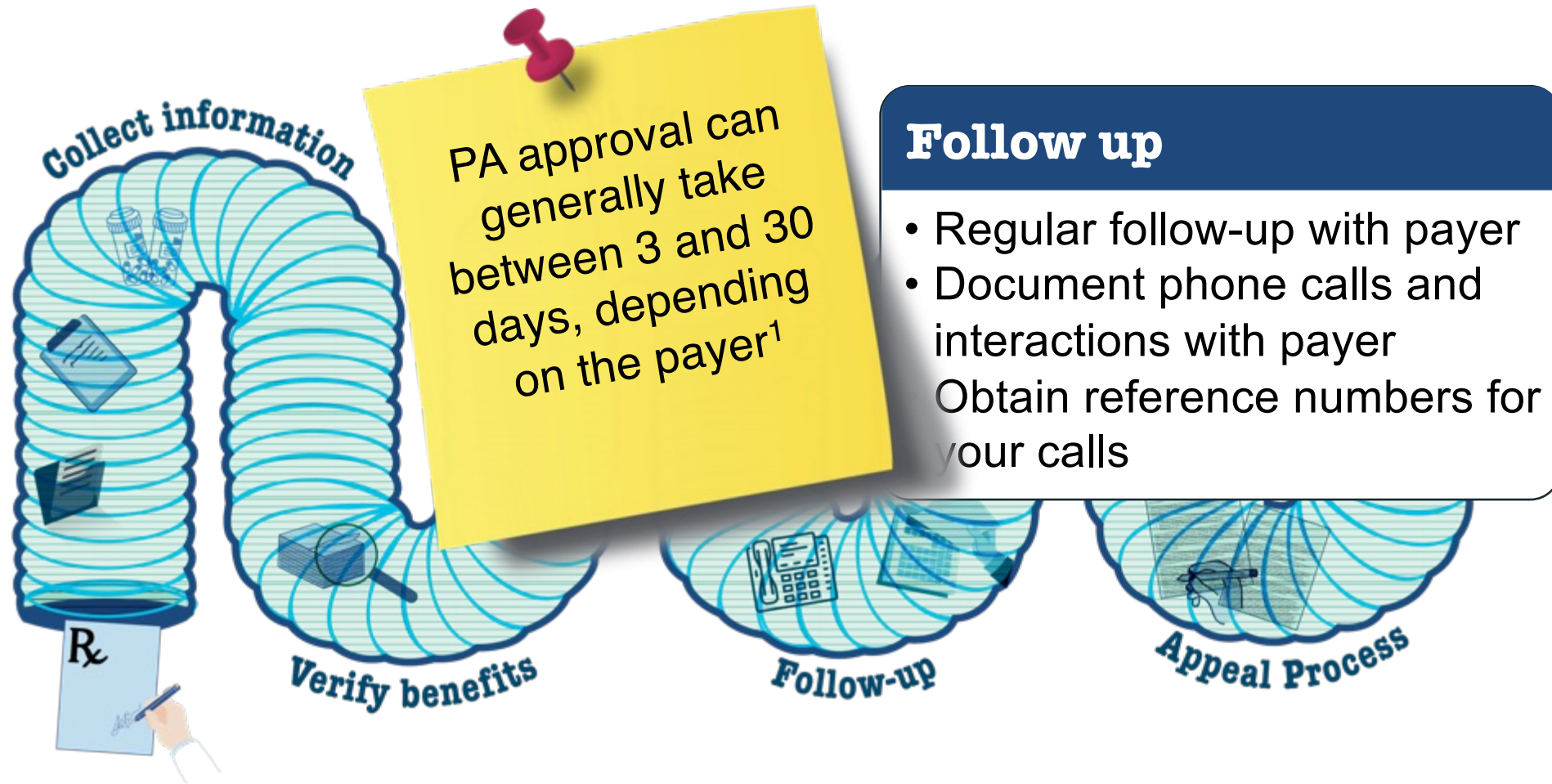
Template letters of medical necessity  
Step therapy protocol reform



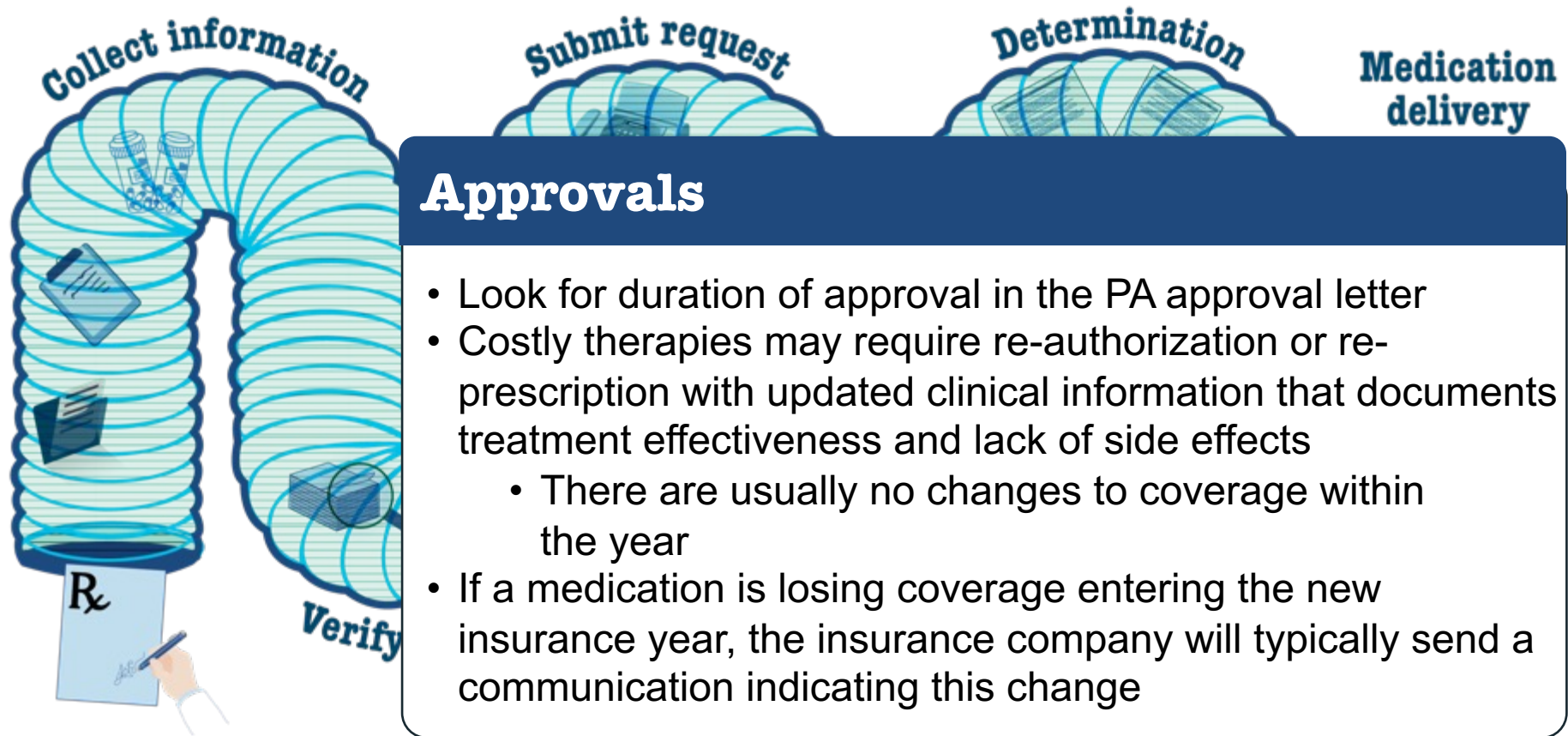
covermymeds®



# The prior authorization process

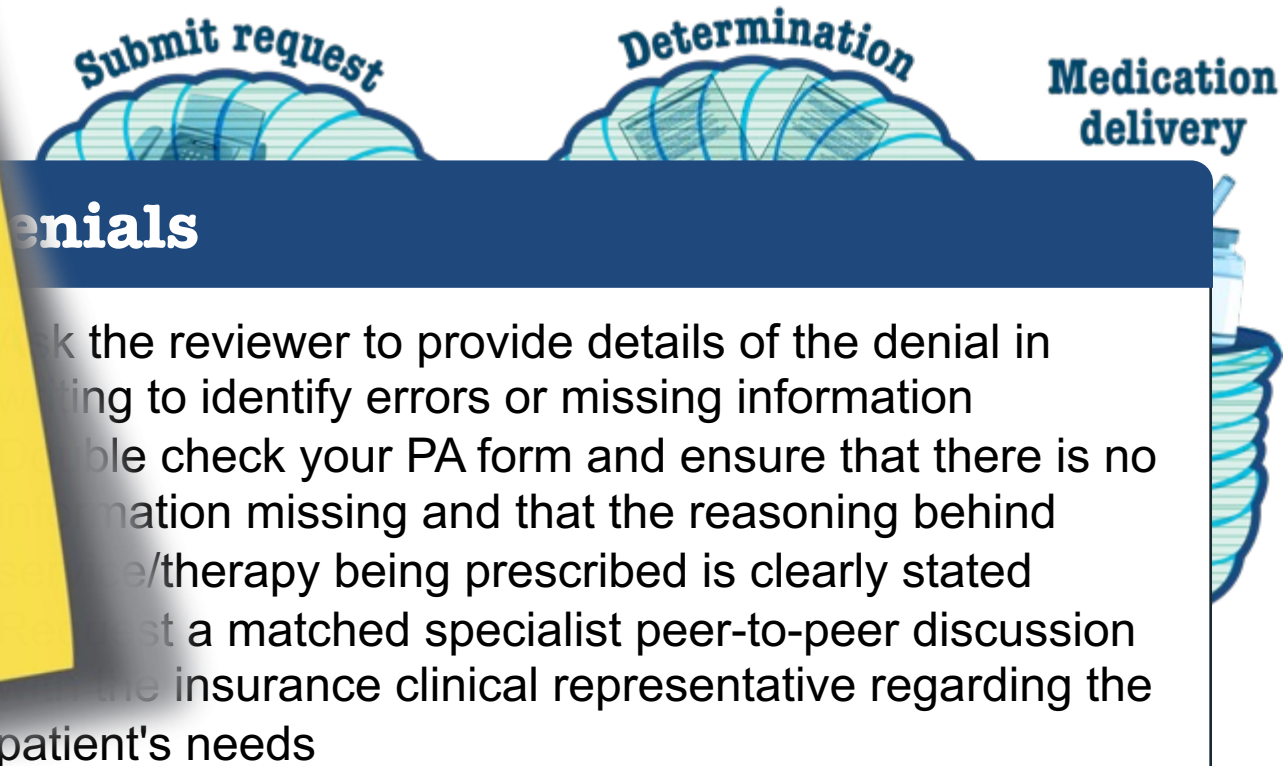


# The prior authorization process: approvals



# The prior authorization process: denials

- Appointments must be requested (not provided on prescriber schedule)
- Peer-to-peer discussions must be conducted by MD, NP, PA, or pharmacist



# Why are therapies denied?

- Biologic & small molecule is nonformulary
- Biologic & small molecule is considered investigational (including off-label usage or dosage)
- Need for stepped care (ie, failure of conventional therapies)
- Patient lack of pharmacy or medical benefits
- Patient <18 years of age
- Incorrect diagnosis

The image shows a 'Medical Claim Form' for Lynne Williams. The form is dated 1/1/2015 and includes a large red 'DENIED' stamp. The form is filled out with the following information:

- PATIENT INFORMATION:** Name: Lynne Williams, Address: 5679 Random Street, City: [blank], State: [blank], Zip: [blank].
- INSURANCE INFORMATION:** Insurance Company: [blank], Policy Number: [blank], Group Number: [blank].
- DIAGNOSIS:** [blank]
- PROCEDURES:** [blank]
- REASON FOR DENIAL:** [blank]

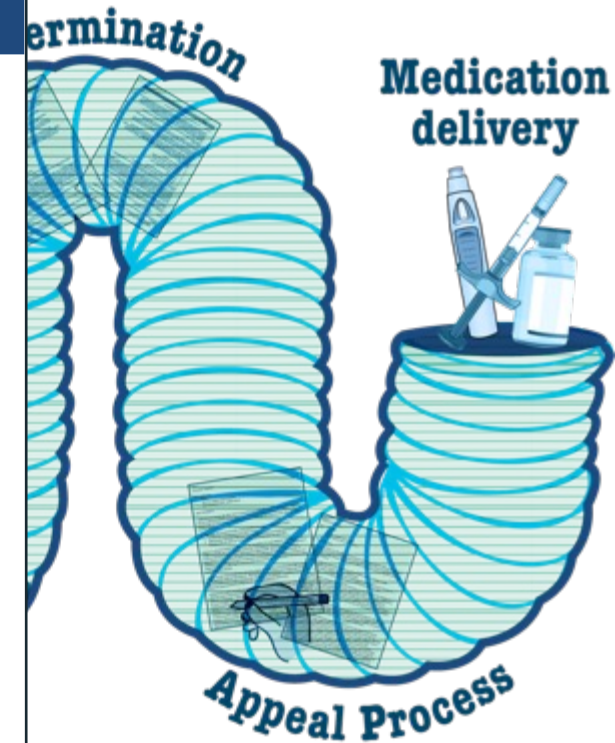
The form also includes a section for the patient's signature and a section for the provider's signature. The patient's signature is 'Lynne Williams' and the provider's signature is 'Lynne Williams'.



# The prior authorization process: appeals

## Appeals

- Be mindful of the timeframe needed to submit and process the appeal (varies by company)
  - If submitted after this timeframe, the appeal will be rejected
- The appeal should include an organized, concise argument supported by clinical data that asks the reviewer to reconsider the decision
- Be aware that insurance companies have different levels to which you can submit an appeal letter
  - Can request second-level appeals, ask for matched specialist



# IBD in the Real World: Appealing for JT



Date  
Insurance Company

RE: JT  
ID no. 12345  
Service: vedolizumab infusions  
Date of service: prior authorization

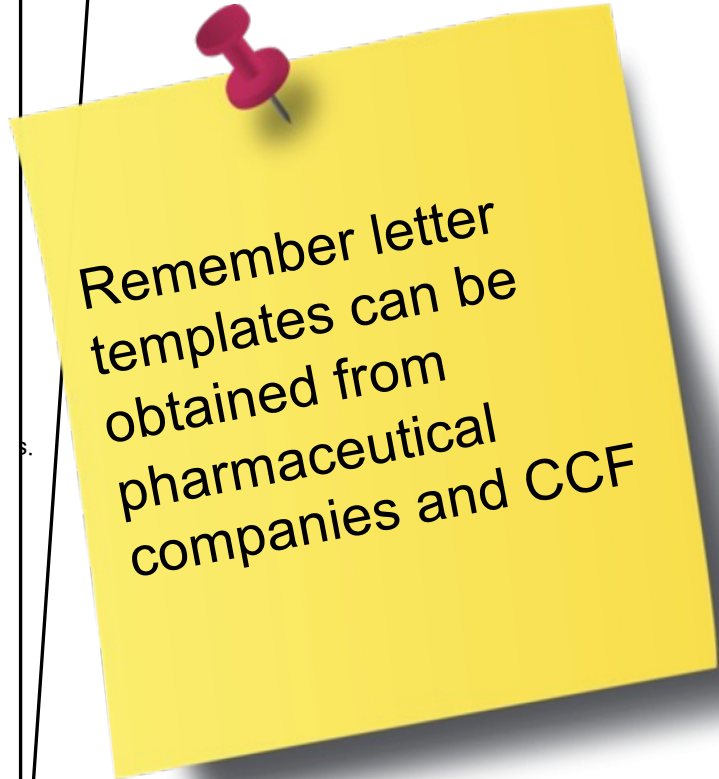
Dear Sir/Madam,

I write to on behalf of Mr. Thompson to request prior authorization for vedolizumab (Entyvio) for the treatment of his moderately active ulcerative colitis. Below is the detailed medical information to support the use of Entyvio to help Mr. Thompson achieve remission.

Mr. Thompson has presented with moderate left-sided ulcerative colitis.

Entyvio is a distinct mechanism from anti-TNF therapies. It is a gut-selective  $\alpha_4\beta_7$  anti-integrin antibody. As such, it is appropriate for many patients both for its unique mechanism of action as well as for its favorable, non-systemic safety profile. There are distinct patient populations in whom it is preferable to consider this therapy prior to anti-TNF therapy. In addition, it is appropriate to switch mechanisms of management when there is a primary non-response to the first anti-TNF therapy, or when the current anti-TNF therapy is not adequately controlling inflammation.

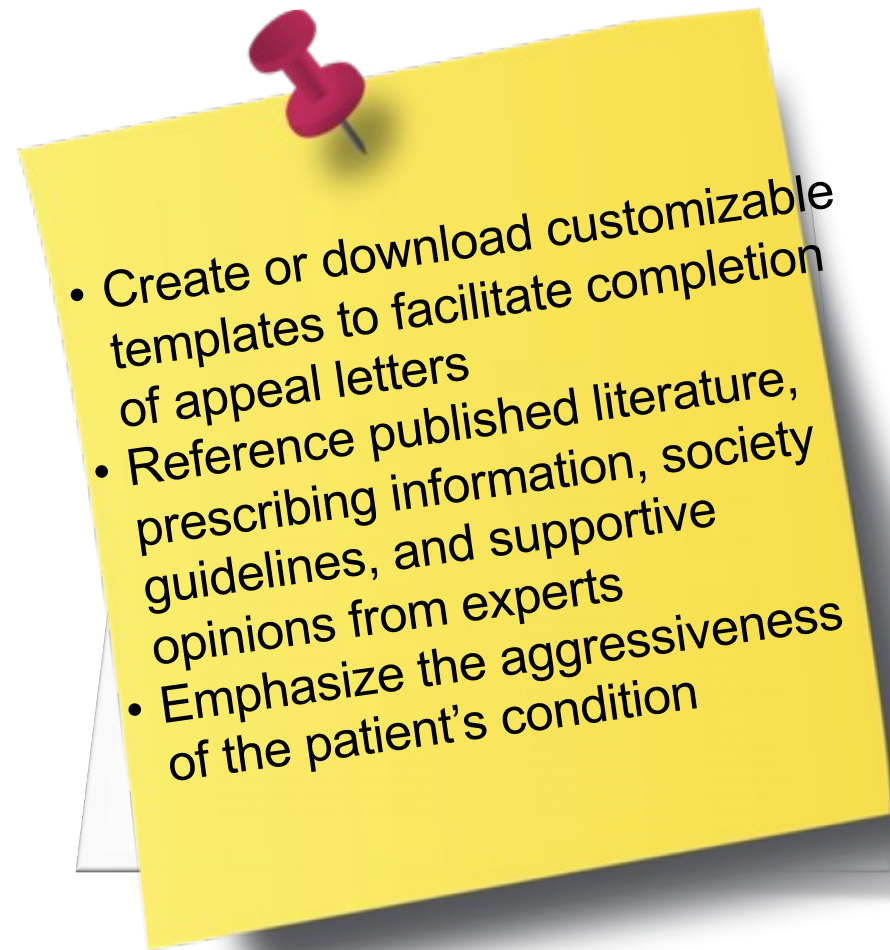
In large clinical trials, Entyvio was effective in both anti-TNF naïve (no prior anti-TNF therapy) and in anti-TNF experienced patients. The Food and Drug Administration (FDA) approved the use of Entyvio in both Crohn's disease and ulcerative colitis patients. In addition, failure of anti-TNF is not required prior to using Entyvio. This is an important distinction.



Remember letter  
templates can be  
obtained from  
pharmaceutical  
companies and CCF

# Letter of medical necessity

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## **Patient history/current diagnosis**

- ✓ Diagnosis codes where appropriate
  - ✓ Clinical findings that led to the diagnosis
  - ✓ Severity of disease
  - ✓ Emphasize parameters for aggressive disease (eg, laboratory results, endoscopic reports, imaging reports)
- 

## **Previous therapy, duration, and outcomes**

- ✓ Specify reasons for unsuccessful results
- 

## **Clear rationale for currently recommended therapy and dosing**

- ✓ Explain how medical care is adversely affected by policies that limit access to requested medication
- ✓ Emphasize how disease may progress, leading to hospitalization/increased cost and impaired quality of life

# When is a biologic medically necessary?

## Anthem Medical Policy

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Initial requests for **vedolizumab** may be approved for the following:

Individual ≥6 years of age with moderate to severe UC or Crohn's disease	+	<b>Inadequate response to, or is intolerant of,</b> or has a contraindication to conventional therapy (eg, systemic corticosteroids or immunosuppressants)
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Requests for **vedolizumab** may not be approved for the following:

- In combination with oral or topical JAK inhibitors, ozanimod, deucravacitinib, or any of the following biologic immunomodulators: Other TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, vedolizumab, ustekinumab, abatacept, rituximab, or natalizumab; OR
- Active, serious infection or a history of recurrent infections; OR
- New or worsening neurological signs or symptoms of John Cunningham virus (JCV) infection or risk of progressive multifocal leukoencephalopathy (PML); OR
- When the above criteria are not met and for all other indications



# When is a biologic medically necessary?

## Aetna Medical Policy

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**Upadacitinib** is considered medically necessary for when the following criteria are met:

Initial requests for **upadacitinib** may be approved for the following:

- |                                    |          |  |
|------------------------------------|----------|--|
| Adult with moderately to severe UC | <b>+</b> | <b>Inadequate response to, is intolerant of, or has contraindication to <math>\geq 1</math> TNF-blocker</b>  |
|                                    |          | <b>OR</b>  |
|                                    |          | <b>Previous use of a biologic (other than TNF blocker) or targeted synthetic drug (eg, tofacitinib) indicated for moderately to severely active UC</b> |

# Tips for successful PAs

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## Identify top payers

in your practice to know which insurance companies to focus on and to gain a better understanding of their formularies and PA processes

## Obtain a copy of payer formularies

online or through fax

## Before initiating the PA process

- Complete an eligibility check to identify the patient's current insurance plan
- Select the appropriate PA form (pharmacy vs medical)

## Before submitting the PA form, consider

- Providing complete medication history including past failed treatments
- Attaching a letter of medical necessity
- Referring to guidelines and/or other reputable sources

**Document every step** of all the PAs submitted by implementing and maintaining a tracking system



# Tying it up: access issues in IBD

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- Recent evidence suggests that early intervention with biologic therapies can help modify disease progression in IBD
- Current treatment algorithms stratify treatment based on patients' risk of complicated disease
- Prior authorization requirements pose a considerable burden for clinicians and patients with IBD and are often inconsistent with recommended IBD treatment strategies
- Key strategies for facilitating approval of biologic therapies in IBD
  - Designate a staff member(s) to manage the logistical details of biologic approvals
  - Regular follow-up to ensure timely approval
  - Submission of well-articulated appeals with supporting clinical information in response to denials
- Resources that can help facilitate timely approval of biologics include specialty pharmacies, CoverMyMeds®, and the CCF



Questions



# IBD

APP & NURSE  
PRECEPTORSHIP

## BREAK

