PA Headaches:

Why Insurance Says No—and How to Make Them Say Yes

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Disclosures

- I have no conflicts with ineligible companies to disclose.

Goals of today's talk

- Why are insurance reviews so challenging?
- Understand criteria & guidelines
- Learn the appeal pathway
- Know who can help
- Avoid common pitfalls

Why Are Insurance Reviews So Challenging?

- **Rules Aren't Universal**
  - Each insurer has its own medical policies
  - Criteria can differ even for the *same* medication or diagnosis
  - Policies change frequently—and often quietly
- **FDA Approval ≠ Automatic Coverage**
  - FDA labeling is only the starting point
  - Payers layer on step therapy, dosing limits, and documentation requirements
  - Missing *one* checkbox can trigger an automatic denial

Why Are Insurance Reviews So Challenging?

- **Medical Necessity Is Interpreted Differently**
  - Clinicians focus on patient-centered care
  - Insurers focus on cost containment and policy compliance
  - Reviews may be done by non-specialists using rigid algorithms
- **Prior Authorization Is Designed to Be a Barrier**
  - Time-consuming forms and phone calls
  - Repetitive documentation requests
  - Delays can outlast clinical urgency
  - Insurers win by saving money on delay-tactics

Why Are Insurance Reviews So Challenging?

- **Appeals Are Complex and Fragmented**
  - Multiple appeal levels with different rules
    - 1st line
    - 2nd line
    - Internal
    - External
  - Strict timelines and submission requirements
  - Many denials succeed simply due to fatigue or time constraints

- **Bottom line:** Insurance reviews are challenging not because the care is inappropriate—but because the system is.

Impact on Patients & Clinical Workflow

- **Impact on Patients**
  - Delays in starting or continuing necessary treatment
  - Worsening symptoms, disease progression, or flares
  - Increased anxiety, frustration, and loss of trust in the system
  - Higher out-of-pocket costs causing abandonment of therapy
  - Patients often blame their provider for denials
    - PBM's often telling patient's it was their doctor who didn't provide proper information.

Impact on Patients & Clinical Workflow

- **Impact on Clinical Workflow**
  - Significant time spent on prior authorizations and appeals
    - Unreimbursed time
  - Repeated documentation, phone calls, and peer-to-peer reviews
  - Staff burnout and moral distress
  - Reduced clinic efficiency
  - Providers pulled away from direct patient care

- **Bottom Line:**
  - ***The true cost of insurance denials isn't just financial—it's clinical time, emotional energy, and patient outcomes.***

Understanding Coverage Criteria

FDA approved indications vs. Policy Criteria

- FDA labeling = baseline requirement
  - FDA approval confirms:
    - Safety and efficacy for a *specific* indication
    - Approved patient population
    - Dosing, frequency, and route of administration
  - FDA labeling defines the **minimum conditions** under which a drug *can* be prescribed
  - Insurers use FDA labeling as the **starting point**, not the final decision
- Payer medical policies may be *more restrictive*
- Importance of always reviewing:
  - FDA prescribing information
  - Payer-specific clinical guidelines
  - Step therapy and prior authorization rules
- If ***any*** element of the FDA label is not met, coverage is usually automatically denied

Infliximab

- 36 year old female has seropositive RA. She has tried and failed methotrexate at maximally tolerated doses. The provider has chosen to start the patient on Infliximab. The patient has a negative tuberculosis test. Infliximab is a formulary alternative. What is an acceptable starting dose?
- A. 5mg/kg every 8 weeks with loading dose in combination with methotrexate
- B. 3mg/kg every 8 weeks with loading dose in combination with leflunomide
- C. 3mg/kg every 8 weeks with loading dose in combination with methotrexate
- D. 3mg/kg every 8 weeks with loading dose
- E. B&C are correct
- F. All of the Above

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0%
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B. 3mg/kg every 8 weeks with loading dose in combination with leflunomide

0%
C. 3mg/kg every 8 weeks with loading dose in combination with methotrexate

0%
D. 3mg/kg every 8 weeks with loading dose

0%
B&C are correct

0%
All of the Above

Infliximab

REMICADE® (infliximab)

- *Ulcerative Colitis:* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. (2.3)
- *Pediatric Ulcerative Colitis (≥ 6 years old):* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. (2.4)
- *Rheumatoid Arthritis:* In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg every 8 weeks or treating as often as every 4 weeks. (2.5)
- *Ankylosing Spondylitis:* 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks. (2.6)
- *Psoriatic Arthritis* and *Plaque Psoriasis:* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. (2.7, 2.8)

Infliximab

- 36 year old female has seropositive RA. The patient has been on Infliximab for 4 months and while she is responding to the medicine some, she still has synovitis on exam and she states that she gets worse 2 weeks prior to the next infusion. What is an acceptable dose escalation?
- A. 5mg/kg every 8 weeks in combination with methotrexate
- B. 3mg/kg every 6 weeks in combination with methotrexate
- C. 5mg/kg every 6 weeks in combination with methotrexate
- D. A&B are correct
- E. B&C are correct
- F. All of the Above.

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- *Psoriatic Arthritis* and *Plaque Psoriasis:* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. (2.7, 2.8)

Adalimumab

- 45 year old female with seropositive RA presents for follow-up. She is currently on methotrexate 20mg once weekly, hydroxychloroquine 400mg daily and Adalimumab 40mg every other week. She is complaining of flares of disease happening weekly over the last 3 months involving joint pain and swelling. She has otherwise done well prior on adalimumab for the last 2 years. You decided you want to increase to weekly Humira. Is this likely to get approved without issues?
- A. Yes
- B. No

Respond at
pe.app/paheadaches

Poll Everywhere

45 year old female with seropositive RA presents for follow-up. She is currently on methotrexate 20mg once weekly, hydroxychloroquine 400mg daily and Adalimumab 40mg every other week. She is complaining of flares of disease happening weekly over the last 3 months involving joint pain and swelling. She has otherwise done well prior on adalimumab for the last 2 years. You decided you want to increase to weekly Humira. Is this likely to get approved without issues?

0 0

Yes 0%

No 0%

Edit

Show Choices Show Responses Lock Show Correctness

Adalimumab

DOSAGE AND ADMINISTRATION

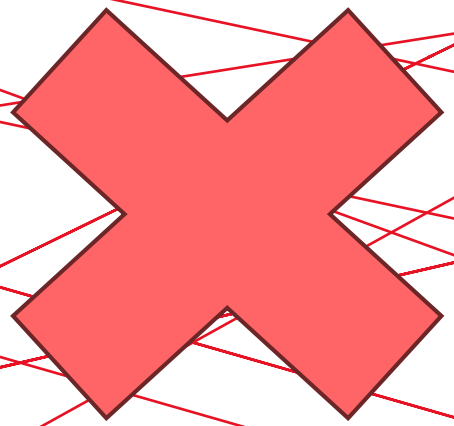
- Administer by subcutaneous injection (2)

Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis (2.1):

- *Adults:* 40 mg every other week.
    - Some patients with RA not receiving methotrexate may benefit from increasing the dosage to 40 mg every week or 80 mg every other week.

Adalimumab Biosimilars

- Amjevita
- Cyltezo
- Hyrimoz
- Yuflyma
- Simlandi
- Hadlima
- Abrilada
- Hulio
- Idacio
- Yusimry



- Adalimumab-afzb
- Adalimumab-aaty
- Adalimumab-aqvh
- Adalimumab-aato
- Adalimumab-fkjp
- Adalimumab-adaz
- Adalimumab-adbm
- Adalimumab-aacf
- Adalimumab-ryvk
- Adalimumab-bwwd

Golimumab (Simponi/Simponi Aria)

- Must be given with Methotrexate (no dose specified) in RA
  - Be extremely cautious if you run an infusion center
    - Medicare can audit and there is no off label review in Medicare.
    - You must be 100% on label. Leflumomide, HCQ or SSZ DO NOT COUNT
    - No ability to say MTX is contraindicated. 1 tab once Monthly IN YOUR NOTE Counts!
    - Do NOT exceed 300 units of Simponi Aria no matter the weight!

---------- **INDICATIONS AND USAGE** ----------

SIMPONI ARIA is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- Adult patients with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate (1.1)
- Active Psoriatic Arthritis (PsA) in patients 2 years of age and older (1.2)
- Adult patients with active Ankylosing Spondylitis (AS) (1.3)
- Active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older (1.4)

Tocilizumab (Actemra/Tyenne/Tofidence)

General Administration and Dosing Information (2.1)

- *RA, GCA, SSc-ILD, PJIA and SJIA* – It is recommended that ACTEMRA not be initiated in patients with an absolute neutrophil count (ANC) below 2000 per mm^3, platelet count below 100,000 per mm^3, or ALT or AST above 1.5 times the upper limit of normal (ULN)*(5.3, 5.4)*.
- *COVID-19* – It is recommended that ACTEMRA not be initiated in patients with an absolute neutrophil count (ANC) below 1000 per mm^3, platelet count below 50,000 mm^3, or ALT or AST above 10 times ULN *(5.3, 5.4)*.
- In *RA, CRS or COVID-19* patients, ACTEMRA doses exceeding 800 mg per infusion are not recommended. (2.2, 2.7, 12.3)
- In *GCA* patients, ACTEMRA doses exceeding 600 mg per infusion are not recommended. (2.3, 12.3)

Rheumatoid Arthritis (RA) (1.1)

- Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).

- Send lab results with prior auth and clinical notes
- Train your prior auth department how to answer the questions of > OR <

Tocilizumab (Actemra/Tyenne/Tofidence)

Recommended Adult Intravenous Dosage:
When used in combination with non-biologic DMARDs or as monotherapy the recommended starting dose is 4 mg per kg every 4 weeks followed by an increase to 8 mg per kg every 4 weeks based on clinical response.

Recommended Adult Subcutaneous Dosage:

Patients less than 100 kg weight	162 mg administered subcutaneously every other week, followed by an increase to every week based on clinical response
Patients at or above 100 kg weight	162 mg administered subcutaneously every week

Giant Cell Arteritis (2.3)
Recommended Adult Intravenous Dosage:
The recommended dose is 6 mg per kg every 4 weeks in combination with a tapering course of glucocorticoids. ACTEMRA can be used alone following discontinuation of glucocorticoids.

Recommended Adult Subcutaneous Dosage:
The recommended dose is 162 mg given once every week as a subcutaneous injection, in combination with a tapering course of glucocorticoids.

A dose of 162 mg given once every other week as a subcutaneous injection, in combination with a tapering course of glucocorticoids, may be prescribed based on clinical considerations.

ACTEMRA can be used alone following discontinuation of glucocorticoids.

Tocilizumab (Actemra/Tyenne/Tofidence)

2.4 Recommended Dosage for Systemic Sclerosis-Associated Interstitial Lung Disease

The recommended dose of ACTEMRA for adult patients with SSc-ILD is 162 mg given once every week as a subcutaneous injection.

- Interruption of dosing may be needed for management of dose-related laboratory abnormalities including elevated liver enzymes, neutropenia, and thrombocytopenia *[see Dosage and Administration (2.11)]*.
- Subcutaneous administration with the prefilled ACTPen® autoinjector has not been studied in SSc-ILD.
- Intravenous administration is not approved for SSc-ILD.

- Policy specific restrictions:
  - Elevated CRP >6mg/mL
  - Patient must have FVC >55%
  - Diagnosis must be confirmed by high-resolution CT

Sarilumab (Kevzara)

INDICATIONS AND USAGE

KEVZARA® is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of:

- adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs). (1.1)
- adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper. (1.2)
- patients who weigh 63 kg or greater with active polyarticular juvenile idiopathic arthritis (pJIA). (1.3)

DOSAGE AND ADMINISTRATION

General Considerations for Administration

- KEVZARA initiation is not recommended in patients with ANC less than 2,000/mm^3, platelets less than 150,000/mm^3 or liver transaminases above 1.5 times ULN. See Full Prescribing Information (FPI) for complete information. (2.1)

Recommended Dosage in RA

- The recommended dosage is 200 mg subcutaneously, once every 2 weeks. (2.2)
- For RA, KEVZARA may be used as monotherapy or in combination with methotrexate (MTX) or other conventional DMARDs. (2.2)

Recommended Dosage in PMR

- The recommended dosage is 200 mg subcutaneously, once every two weeks in combination with a tapering course of corticosteroids. (2.3)
- For PMR, KEVZARA can be used as monotherapy following discontinuation of corticosteroids. (2.3)

Rituximab (Rituxan, Truxima, Riabni, Ruxience)

- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies (1.3).
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids (1.4).

Dosing for GPA/MPA: 375mg/m2 weekly x 4 weeks, then 6 months later 500mg day 0 and day 14, then 500mg every 6 months thereafter.

- Anything else is OFF LABEL.

Tofacitinib (Xeljanz)/Upadacitinib (Rinvoq)/Baricitinib (Olumiant)

INDICATIONS AND USAGE

XELJANZ (tablets and oral solution) and XELJANZ XR (extended-release tablets) are Janus kinase (JAK) inhibitors.
XELJANZ tablets and XELJANZ XR are indicated for the treatment of adult patients with:

- **Moderately to severely active rheumatoid arthritis (RA),** who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active psoriatic arthritis (PsA),** who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active ankylosing spondylitis (AS),** who have had an inadequate response or intolerance to one or more TNF blockers.
- **Moderately to severely active ulcerative colitis (UC),** who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations of Use:

- Use of XELJANZ/XELJANZ XR for RA, AS, PsA, or pcJIA in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended. (1.1, 1.2, 1.3, 1.4)

DOSAGE AND ADMINISTRATION

Recommended Evaluations and Immunization Prior to Treatment Initiation

- Prior to initiating XELJANZ/XELJANZ XR, consider performing an active and latent TB evaluation, viral hepatitis screening, a complete blood count, and updating immunizations. Avoid XELJANZ or XELJANZ XR initiation if absolute lymphocyte count <500 cells/mm^3, an absolute neutrophil count (ANC) <1000 cells/mm^3 or hemoglobin <9 g/dL. (2.1)

- Avoid initiation or interrupt RINVOQ/RINVOQ LQ if absolute lymphocyte count is less than 500 cells/mm^3, absolute neutrophil count is less than 1000 cells/mm^3, or hemoglobin level is less than 8 g/dL. (2.1, 2.14)

Secukinumab (Cosentyx)

- **Plaque Psoriasis:**
  - *Subcutaneous Dosage in Adults:* Recommended dosage is 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. For some patients, a dose of 150 mg may be acceptable. (2.3)
  - *Subcutaneous Dosage in Pediatric Patients 6 Years and Older:* Recommended weight-based dosage is administered by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
    - For patients < 50 kg (at the time of dosing), the dose is 75 mg.
    - For patients ≥ 50 kg (at the time of dosing), the dose is 150 mg. (2.3)
- **Psoriatic Arthritis:**

  Adult Patients

  Subcutaneous Dosage:
  - For PsA patients with coexistent moderate to severe PsO, use the dosage and administration for PsO. (2.3)
  - For other PsA patients, administer with or without a loading dosage.
    - With a loading dosage: 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter
    - Without a loading dosage: 150 mg every 4 weeks
    - If a patient continues to have active PsA, consider a dosage of 300 mg every 4 weeks. (2.4)

Secukinumab (Cosentyx)

Intravenous Dosage:
The recommended intravenous dosages are:
- With a loading dosage: 6 mg/kg given at Week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter (max. maintenance dose 300 mg per infusion).
- Without a loading dosage: 1.75 mg/kg every 4 weeks (max. maintenance dose 300 mg per infusion). (2.4)

- **Ankylosing Spondylitis:**

Subcutaneous Dosage:
Administer with or without a loading dosage.
The recommended dosages are:
- With a loading dosage: 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
- Without a loading dosage: 150 mg every 4 weeks.
- If a patient continues to have active ankylosing spondylitis, consider a dosage of 300 mg every 4 weeks. (2.6)

- **Non-Radiographic Axial Spondyloarthritis:**

Subcutaneous Dosage:
Administer with or without a loading dosage. The recommended dosage is:
- With a loading dosage: 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
- Without a loading dosage: 150 mg every 4 weeks. (2.7)

Ixekizumab (Taltz)

Adult Plaque Psoriasis (2.2)
- Recommended dosage is 160 mg (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks.

Pediatric Plaque Psoriasis (2.3)
- For patients weighing greater than 50 kg, recommended dosage is 160 mg (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.
- For patients weighing 25-50 kg, recommended dosage is 80 mg at Week 0, followed by 40 mg every 4 weeks.
- For patients weighing less than 25 kg, recommended dosage is 40 mg at Week 0, followed by 20 mg every 4 weeks.

Psoriatic Arthritis (2.4)
- Recommended dosage is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.
- For psoriatic arthritis patients with coexistent moderate-to-severe plaque psoriasis, use the dosing regimen for adult plaque psoriasis. (2.2)
- TALTZ may be administered alone or in combination with a conventional DMARD (e.g., methotrexate).

Ankylosing Spondylitis (2.5)
- Recommended dosage is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.

Non-radiographic Axial Spondyloarthritis (2.6)
- Recommended dosage is 80 mg by subcutaneous injection every 4 weeks.

Bimekizumab (Bimzelx)

- **Plaque Psoriasis**
  - Administer 320 mg by subcutaneous injection at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter. For patients weighing 120 kg or more, consider a dose of 320 mg every 4 weeks after Week 16. (2.2)
- **Psoriatic Arthritis**
  - Administer 160 mg by subcutaneous injection every 4 weeks. (2.3)
  - For patients with coexisting moderate to severe plaque psoriasis, use the dosage and administration for plaque psoriasis. (2.2)
- **Non-Radiographic Axial Spondyloarthritis**
  - Administer 160 mg by subcutaneous injection every 4 weeks. (2.4)
- **Ankylosing Spondylitis**
  - Administer 160 mg by subcutaneous injection every 4 weeks. (2.5)

Ustekinumab (Stelara, Yesintek, Wezlana, Pyzchiva, Selarsdi, Steqeyma)

Adult Patients with Plaque Psoriasis Subcutaneous Recommended Dosage (2.1):

Weight Range (kilograms)	Dosage
less than or equal to 100 kg	45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks
greater than 100 kg	90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks

Pediatric Patients 6 Years of Age and Older with Plaque Psoriasis Subcutaneous Recommended Dosage (2.1): Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter.

Weight Range (kilograms)	Dose
less than 60 kg	0.75 mg/kg
60 kg to 100 kg	45 mg
greater than 100 kg	90 mg

Psoriatic Arthritis Adult Subcutaneous Recommended Dosage (2.2):

- The recommended dosage is 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks.
- For patients with co-existent moderate-to-severe plaque psoriasis weighing greater than 100 kg, the recommended dosage is 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks.

Belimumab (Benlysta)

---------- **INDICATIONS AND USAGE**----------

BENLYSTA is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of patients 5 years of age and older with:

- Active systemic lupus erythematosus (SLE) who are receiving standard therapy; (1)
- Active lupus nephritis who are receiving standard therapy. (1)

Limitations of Use:

The efficacy of BENLYSTA has not been evaluated in patients with severe active central nervous system lupus. Use of BENLYSTA is not recommended in this situation. (1)

- **Send Lab results**
  - Show ANA >1:80 or DsDNA >30 IU/mL
- SELENA-SLEDAI >6
- Some policies may require failure of HCQ and another conventional DMARD despite recent EULAR recommendations.

Anifrolumab-fnia (Saphnelo)

---------- INDICATIONS AND USAGE ----------

SAPHNELO is a type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy. (1)

Limitations of Use: The efficacy of SAPHNELO has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of SAPHNELO is not recommended in these situations. (1)

The Appeal Pathway and Know Who Can Help

Steps of Denial

- 1st Denial
  - Non-medical, checking boxes only
  - Submit updated clinical notes, criteria met, medical necessity letter
- 2nd Denial
  - Internal review
  - Often reviewed by a different department or medical director
- External Review/Independent Medical Review
  - State-regulated
  - Reviewer not employed by the insurance company
  - Decision is typically binding

How Do We Decrease First-Level Denials?

- **Know the Exact FDA Language**
  - Review the FDA-approved indication before submitting PA
  - Match:
    - Diagnosis wording
    - Patient population (age, severity, subtype)
    - Dosing and frequency
  - Use *similar terminology* in your note and PA submission
  - If the label says "moderate-to-severe," document objective criteria that support it

How Do We Decrease First-Level Denials?

- **Submit Complete Supporting Data Up Front**
  - Include required labs (with dates)
  - Imaging reports
  - Disease activity scores (if applicable)
  - Weight/BMI when dosing is weight-based
  - Avoid "labs available upon request" — send them proactively
- **Clearly Document All Trials and Failures**
  - List:
    - Medication name
    - Dose
    - Duration
    - Reason for discontinuation (ineffective, adverse effects, contraindication)
  - Document intolerance specifically (e.g., transaminitis, cytopenia, severe GI intolerance)
  - If step therapy required, clearly show step completion

How Do We Decrease First-Level Denials?

appeals provider's note, pt has tried and failed Humira. *Criteria not met: Provider indicated pt has tried and failed Methotrexate taps and injection, date and duration of trial unknown. Provider also indicated pt has tried and failed Humira Pen, Xejanz XR, and Orencia. However, submitted medical record and claim history do not document drug, date, and duration of therapy, thus criteria is not met. Provider did NOT acknowledge that patient has a

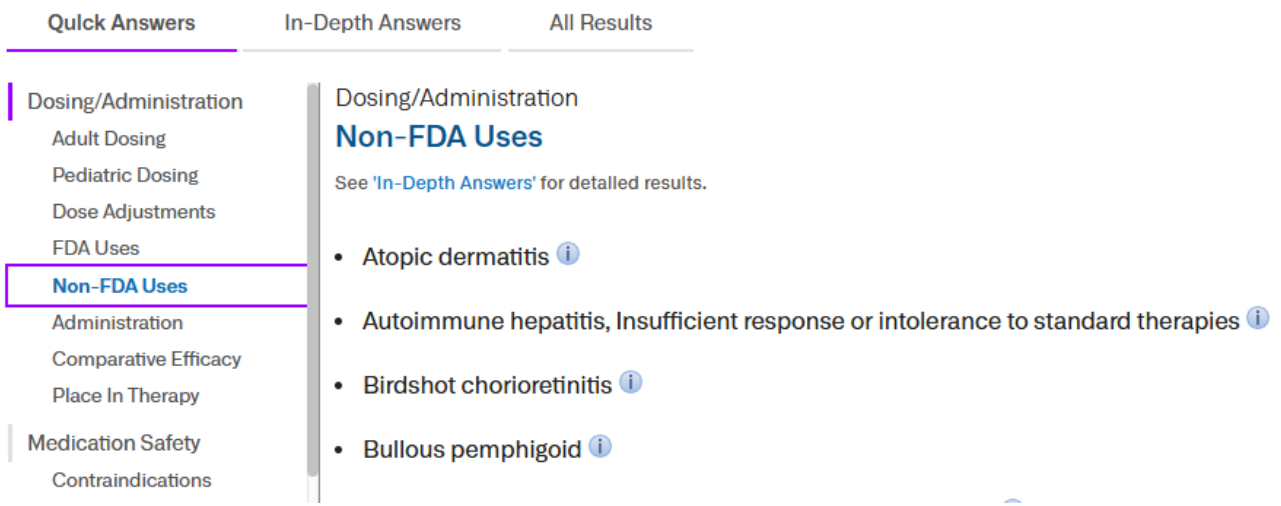
Make the Reviewer's Job Easy

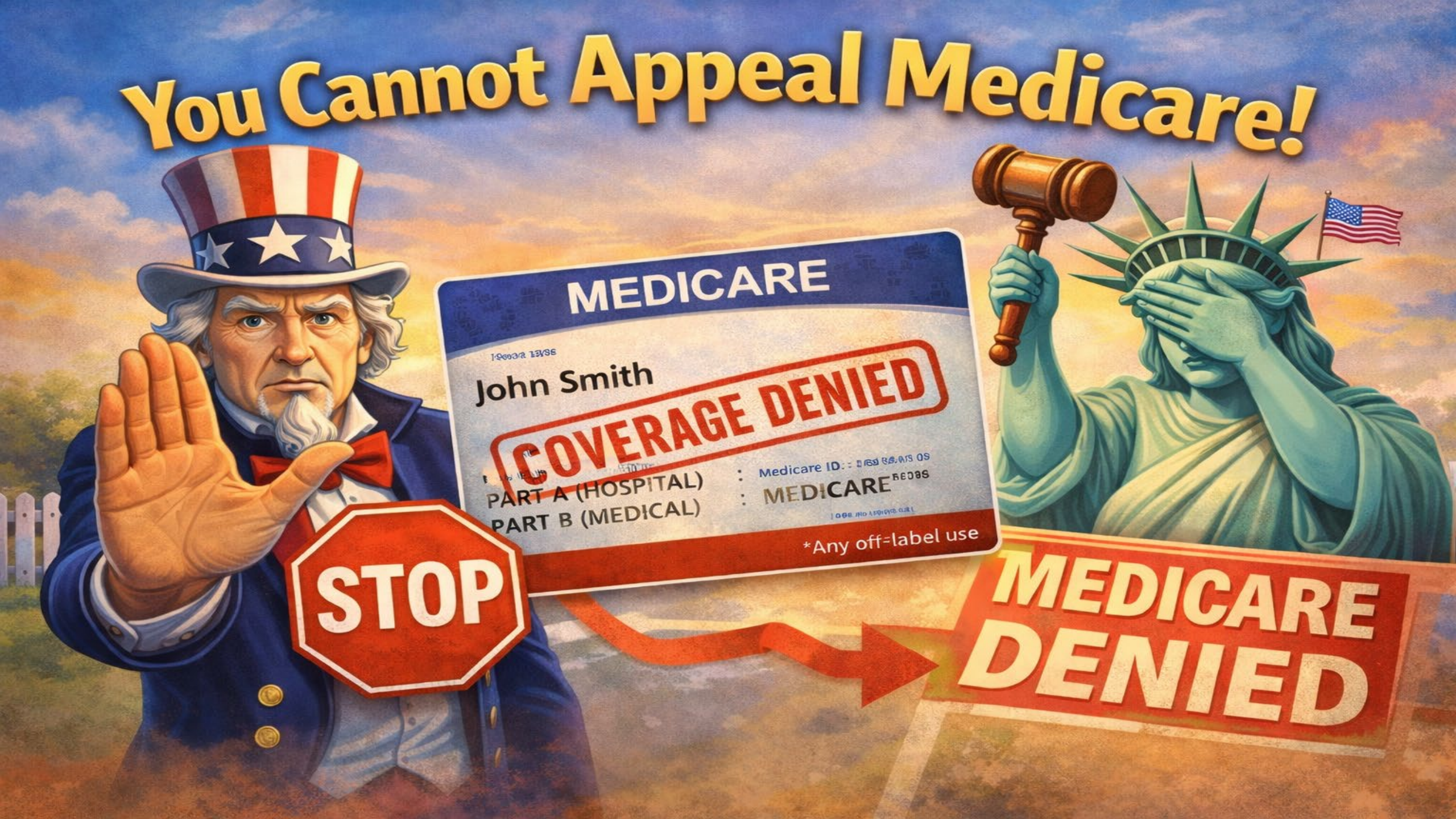
- **Many first-level denials are preventable — they are documentation denials, not medical denials.**

- When you have to appeal a denial
  - Use a brief summary section in your note:
    - Document why every part of the denial is irrelevant for your patient
    - Bullet-point criteria alignment
      - If it lists multiple meds patient must try/fail – say why each one is not appropriate for your patient
    - Avoid vague language like "failed multiple meds"

Medicare Appeals

- You CAN NOT appeal for off label
  - Medicare legally bound to CMS guidelines and compendia
    - Must be compendia supported by level IIb evidence of higher
    - American Hospital Formulary System Drug Information
    - Micromedex DRUGDEX
  - Even external reviewers cannot override CMS law
  - If off-label, Medicare denial = final




You Cannot Appeal Medicare!
MEDICARE
John Smith
COVERAGE DENIED
PART A (HOSPITAL)
PART B (MEDICAL)
MEDICARE
*Any off-label use
STOP
MEDICARE DENIED

Who Can Help With Appeals

- Internal Allies
  - Prior authorization team / billing specialists
  - Clinic nurses who manage documentation
  - Provider writing the medical necessity narrative
  - Specialty pharmacy and manufacturer patient-assistance reps

Insurance Portals

- Why Insurance Portals Are Essential?
  - Faster prior authorization submissions
  - Real-time status updates (no more guessing)
  - Direct access to denial reasons and criteria
  - Ability to upload labs, notes, and appeal documents
  - Fewer phone calls and faxes
- Utilize programs like Cover My Meds
  - Prompted questions that sometimes guide you right into formulary options
- Insurance portals for BCBS, UHC, etc
  - Allows evaluation of claims
  - Ask and track questions
  - Prove documentation was received timely.

Insurance Portals

- Allow for chat features to attach supporting documentation, ask for re-evaluation.
- Example: Thanks for contacting Wellmark. We conducted a review of the claim you referenced. After reviewing the claim, we have determined that Stand on processing of claim 41166278490; The billed drug code, J3489 , was denied because it was not billed with an approved diagnosis, per our policy, which is based on the FDA-approved package insert/prescribing information, the pharmaceutical compendia, and CMS Policy. According to our policy, which is based on the FDA-approved package insert/prescribing information, the pharmaceutical compendia, and CMS Policy, zoledronic acid is appropriate for certain FDA-approved and non-FDA-approved indications. Zoledronic acid is indicated for the treatment of bone metastases, early breast cancer in women with postmenopausal reproductive hormone levels, glucocorticoid-induced osteoporosis, hypercalcemia of malignancy, liver transplant, monoclonal gammopathy of uncertain significance with osteopenia or osteoporosis, multiple myeloma, myositis ossificans, osteitis deformans [Paget's disease], osteoporosis in men, postmenopausal osteoporosis prophylaxis, postmenopausal osteoporosis treatment, postmenopausal women taking letrozole for early breast cancer, prostate cancer patients receiving androgen deprivation therapy, secondary fracture prophylaxis, Osteogenesis imperfecta and Volkmann's ischemic contracture. If you have any questions, please reply to this message or submit another question. Sincerely, Wellmark Customer Service.


APPROVED

Who Else Can Help?

- External Allies:
  - State Insurance Commissioner
    - Must file in the state the policy resides in
    - Can help trigger expedited reviews
  - Patient Advocacy Groups & Facebook Support Pages
    - Reach out to them on their Facebook Account
      - Private Message them
    - CSRO
      - https://csro.info/forms/insurance_notification.php
    - ACR
      - EMAIL: practice@rheumatology.org
  - Senators
    - Can pressure insurers on wrongful denials

Avoid Common Pitfalls

Practical Tools & Best Practices

- Documentation Strategies
  - Keep template letters for common denials
  - Maintain a “criteria checklist” per insurer
    - What common formulary medications
    - What test results they need with review
  - Document all failed therapies and side effects
    - Build on your list in your note with each med tried
  - Stay current on updates to FDA labeling and payer policies

Practical Tools & Best Practices

- Pre-Emptive Approaches
  - Know payer rules *before* prescribing
  - Avoid incomplete forms or missing documentation
  - Ensure coding accuracy to prevent administrative denials

Key Takeaways

- Always start with FDA labeling & payer-specific rules
- Medicare cannot approve off-label indications
- Appeals are a multi-step process—don't skip levels
- Many resources can support appeals
- Strategic documentation = fewer denials


Questions?
Anything We Didn't Cover?
STOP
APPEAL
CVS Caremark
MEDICARE
COVERAGE DENIED
*Any off-label use
INSURANCE COMMISSIONER
OptumRx
LEVEL 1
LEVEL 2
EXTERNAL REVIEW
DENIED