Medical Speakers

Jeffrey Stark, MD
Head of U.S. Medical Affairs – Rheumatology
UCB Pharma
Smyrna, GA

Anca Pop, MD
Head of U.S. Medical Affairs – Gastroenterology
UCB Pharma
Smyrna, GA
Disclosure Information

• This is an educational program sponsored by UCB
• All speakers and workshop facilitators are employees of UCB
• The information contained within this presentation is for your educational purposes only. The examples of advocacy are based on expert opinion and are not directive of engagement in advocacy activities
• Although patient cases within this presentation are based on real-life scenarios, the patient identities are fictional and for illustrative purposes only. They are not intended to suggest the use of any specific treatments or classes of therapy
• Healthcare providers should exercise their professional judgment when treating their own patients
• Describe the burden of disease and evaluate the challenges associated with obtaining appropriate health care in patients with chronic inflammatory diseases

• Recognize opportunities available for healthcare providers to advocate for patients with chronic inflammatory diseases

• Advocacy workshop: Identify specific advocacy strategies to address the identified challenges of this patient population
THE IMPACT OF CHRONIC INFLAMMATORY DISEASES
Key Issues for Patients With nr-axSpA

- ~350 of every 100,000 US adults are living with nr-axSpA
- Of patients with nr-axSpA, ~57% are women
- Patients with axSpA wait an average of ~5-8 years for a diagnosis
- During this time, patients see multiple different specialists and may receive misdiagnoses and potentially inappropriate or ineffective therapies
- There is no ICD code for nr-axSpA, which can create barriers to insurance coverage for appropriate therapies
- Patients with axSpA are much less likely to receive a biologic therapy than are patients with RA
- 27% of patients with axSpA receive chronic opioid therapy. Among these patients, 43% receive opioid monotherapy
- 45% of patients with axSpA switch to a less physically demanding job
- 24% of patients with axSpA leave the workforce early

axSpA, axial spondyloarthritis; ICD, International Classification of Diseases; nr-axSpA, non-radiographic axial spondyloarthritis; RA, rheumatoid arthritis.

nr-axSpA Patient Journey
Kyra, 32 years old, Graphic Designer

For a few months, Kyra experiences back pain that improves with exercise, joint stiffness in her hands, and some fatigue.

Her back pain and joint stiffness continue to worsen 2.5 years ago.

An ophthalmologist diagnoses an episode of anterior uveitis and then refers her to a rheumatologist.

The rheumatologist diagnoses her with nr-axSpA but selects an ICD-10 code of M46.90 for unspecified inflammatory spondylopathy as there is no ICD code for nr-axSpA.

Her back pain and joint stiffness continue to worsen 6 months ago.

3 months ago, the rheumatologist refers her to a pain specialist who prescribes opioids.

Worsening joint symptoms in her hands, lack of sleep, and fatigue make it difficult for her to socialize. Worsening back pain makes it difficult for Kyra to sit in front of her computer for extended periods while at work, so she recently reduced her hours.

Over a span of 2 years, she visits a chiropractor for several sessions, but her back pain does not improve.

Her symptoms persist, and she has a hard time sleeping and working.

She visits her PCP and is prescribed NSAIDs, which lead to some improvement.

Initial symptoms
Persistent symptoms and impact
Worsening symptoms
Worsening symptoms and life impact

Initial treatments
Modified treatment
Referral to pain management
Referral to rheumatologist
Lack of an ICD code for nr-axSpA
Denied insurance coverage

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
For a few months, Kyra experiences back pain that improves with exercise, joint stiffness in her hands, and some fatigue.

Her symptoms persist, and she has a hard time sleeping and working.

Worsening joint symptoms in her hands, lack of sleep, and fatigue make it difficult for her to socialize. Worsening back pain makes it difficult for Kyra to sit in front of her computer for extended periods while at work, so she recently reduced her hours.

Over a span of 2 years, she visits a chiropractor for several sessions, but her back pain does not improve.

She visits her PCP and is prescribed NSAIDs, which lead to some improvement.

Her PCP refers her to a pain specialist who prescribes opioids.

An ophthalmologist diagnoses an episode of anterior uveitis and then refers her to a rheumatologist.

The rheumatologist diagnoses her with nr-axSpA but selects an ICD-10 code of M46.90 for unspecified inflammatory spondylopathy as there is no ICD code for nr-axSpA.

Kyra’s insurance provider denied coverage for her prescribed therapy as it is not indicated for the M46.90 diagnostic code selected by her rheumatologist.

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
Key Issues for Patients With PSO-PsA

- ~7 million adults in the United States live with psoriasis (PSO)\(^1\)
- ~1-3 million individuals in the United States live with psoriatic arthritis (PsA)\(^2,3\)
- Almost one-third of those with PSO develop PsA\(^4\)
- 85% of patients develop PSO prior to PsA\(^5\)
- ~70%-80% of dermatologists do not prescribe biologic therapies for patients with PSO or PsA\(^6\)
- Compared with the general population, patients with PSO are~40% more likely to experience depression and suicidality\(^7\)
- Patients with PsA have more than double the rate of depression as patients with PSO alone\(^8\)
- Patients with PSO have a lower rate of depression when their disease is controlled\(^9\)

In general, access to appropriate support for mental health can be a challenge\(^10\)

---

10

PSO-PsA Patient Journey
Jocelyn, 35 years old, Cosmetologist

Initial symptoms

Work and personal impact

4.5 years ago

Work and social impact

3 years ago

Worsening symptoms

2.5 years ago

Financial and personal impact

6 months ago

Worsening symptoms

1 year ago

Referral to rheumatologist and biologic coverage denial

3 months ago

Initial treatment

Phototherapy and insurance

Modified treatment

Today

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
Her disease makes her feel anxious and self-conscious in public and with her clients. She has faced rejection from potential romantic partners due to her skin condition. Jocelyn, 35 years old, Cosmetologist

Symptoms persist, and she now has plaques on >30% of her body. She also starts having some joint stiffness, which she attributes to the requirements of working with her hands to do her job. Worsening joint stiffness causes her to further reduce her work schedule. She is anxious about being unable to do her job. The pain and burning make it difficult to sleep.

Her dermatologist prescribes topical therapy. The cream is difficult to apply in certain areas, and it does not result in clear skin. She struggles to find time for her treatments, which forces her to reduce her work schedule. She is increasingly depressed and has retreated from all social activities.

There are no questions on joint issues on her intake form, and Jocelyn does not discuss her joint symptoms with her dermatologist. He prescribes systemic steroids for the worsening skin symptoms.

Her dermatologist adds phototherapy to her regimen, which results in limited improvement. To afford her treatments, she purchases health insurance through her membership in a professional beauty organization.

After mentioning her joint symptoms to her dermatologist, Jocelyn is referred to a rheumatologist who diagnoses her with PsA and prescribes methotrexate and a biologic.

Her insurance provider denies coverage for the biologic, citing a requirement that she fail multiple lines of systemic therapy before she can be eligible for biologics. She is in financial hardship, is depressed, and continues to have both joint and skin symptoms.

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
Key Issues for Patients With Crohn’s Disease

• ~2 million patients in the United States live with inflammatory bowel disease (IBD)1

• ~800,000 patients in the United States live with Crohn’s disease (CD)1

• Generally, step-up therapy is recommended by the ACG and AGA treatment guidelines and is preferred by payers2-5

• For patients with factors suggestive of an aggressive disease course, a top-down approach may be considered2,6

• Medical nutrition therapy may be prescribed by physicians but may not be covered by insurance7-9

High out-of-pocket costs may contribute to nonadherence10-12

Patients with CD may experience fear of incontinence, reduced social function, loss of productivity, and psychological stress13-17

Inadequate access to bathrooms can be a major challenge16,17

ACG, American College of Gastroenterology; AGA, American Gastroenterological Association.


CD Patient Journey
Tobias, 20 years old, Barista and College Student

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
CD Patient Journey

Tobias, 20 years old, Barista and College Student

Tobias experiences ~3 liquid or watery stools per day, and he sporadically experiences some pain and cramping.

His symptoms worsen, and he experiences ≥7 liquid or watery stools per day and complains of moderate pain and cramping. He starts arriving late to work, missing some classes, and opting out of social activities.

At work, he takes frequent bathroom breaks, which irritates his supervisor, coworkers, and customers. At college, he is unable to easily find a private bathroom, and he feels embarrassed while using shared facilities.

Despite treatment, he continues to experience abdominal pain and diarrhea. Active disease affects his work performance, and he is fired from his job. Active disease also prevents him from taking his mid-semester exams, and he is in danger of failing a number of classes.

Concluding that Tobias has failed the initial therapies, his physician prescribes a biologic. Insurance covers the biologic, but the co-pays are high. Tobias is unsure that he can afford both his college expenses and the cost of therapy. He is also disheartened that a lack of facilities is impacting his success at college and his opportunities to work.

Once Tobias graduates, he may come off his parents’ health insurance. He is concerned about affording insurance and changes in coverage of his treatments.

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
Key Issues for Women of Childbearing Potential

1 in 5 individuals in the United States with RA, ankylosing spondylitis (AS), PsA, PSO, or CD is a woman of childbearing potential. Compared with men with these diseases, women with chronic inflammatory diseases report lower quality of life, higher rates of depression and anxiety, and lower sexual satisfaction and function. Women with chronic inflammatory diseases are concerned about the heritability of the disease and the possible impact of certain agents on a woman’s reproductive journey. Although there are therapies with clinical evidence relating to women of childbearing potential that women and their HCPs can consider in shared decision making, payer step edits may limit access to these options. Active disease may be associated with negative pregnancy outcomes. It is important to achieve disease control in all women of childbearing potential as ~50% of pregnancies in the general population are unplanned.

HCPs, healthcare providers.

Woman of Childbearing Potential Patient Journey
Meera, 30 years old, College Professor

Meera experiences severe disease symptoms associated with her chronic inflammatory disease, which affect her daily life, ability to enjoy hobbies, and ability to socialize with friends. She has a disease flare within a few weeks of giving birth. Despite active disease postpartum, she decides against restarting her therapy while breastfeeding her infant son. She unexpectedly finds out that she is pregnant 1 year ago. She decides to stop her therapy without discussing the decision with her physician, especially because she feels the treatment is not working. Despite feeling well during the first 6 months of therapy, she starts to experience symptoms again and feels poorly 1.5 years ago. Her insurance provider changes its formulary and no longer covers her therapy. She is forced to settle for another agent 8 to 5 months ago. Her physician intermittently prescribes steroids to manage the flares. She discusses therapeutic options with her doctor that will support her life goals, including traveling internationally and starting a family in the future. She is uncomfortable with some therapies, given the chance she could become pregnant. She and her physician select an agent that her insurance provider covers.

Initial symptoms → Worsening symptoms → Pregnancy → Disease flares → High risk pregnancy due to uncontrolled disease activity → Life impact

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
Woman of Childbearing Potential Patient Journey
Meera, 30 years old, College Professor

Meera experiences severe disease symptoms associated with her chronic inflammatory disease, which affect her daily life, ability to enjoy hobbies, and ability to socialize with friends.

2.5 years ago
Her insurance provider changes its formulary and no longer covers her therapy. She is forced to settle for another agent.

2 years ago
She discusses therapeutic options with her doctor that will support her life goals, including traveling internationally and starting a family in the future. She is uncomfortable with some therapies, given the chance she could become pregnant. She and her physician select an agent that her insurance provider covers.

1.5 years ago
Despite feeling well during the first 6 months of therapy, she starts to experience symptoms again and feels poorly.

1 year ago
She unexpectedly finds out that she is pregnant.

8 to 5 months ago
Her disease flares multiple times during pregnancy.

4 months ago
Her physician intermittently prescribes steroids to manage the flares.

2 months ago
Meera enters the third trimester. Her physician counsels that she is in the high risk pregnancy category because of her uncontrolled disease activity.

Today
She is worried about her ability to simultaneously take care of her family and cope with her disease.

She has a disease flare within a few weeks of giving birth. Despite active disease postpartum, she decides against restarting her therapy while breastfeeding her infant son.

1.5 years ago
She decides to stop her therapy without discussing the decision with her physician, especially because she feels the treatment is not working.

1 year ago
Her physician intermittently prescribes steroids to manage the flares.

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
Patient Profiles: Summary of Key Challenges

How can we help Meera avoid unnecessary non-medical switching?

How can we help Tobias receive better access to facilities?

How can we help Jocelyn get earlier access to effective therapy for her disease?

How can we help Kyra access the most appropriate therapy for nr-axSpA?
ADVOCACY FOR PATIENTS WITH CHRONIC INFLAMMATORY DISEASES
Kristi Lengyel
Head of US Patient Advocacy
UCB Pharma
Smyrna, GA
What is advocacy?

ADVOCACY

- Community development
- Education & awareness
- Research
- Lobbying
Why is advocacy important?

Total Federal Bills and Resolutions Introduced Each Congress\(^1\)

<table>
<thead>
<tr>
<th>Congress</th>
<th>Number Filed</th>
</tr>
</thead>
<tbody>
<tr>
<td>116th</td>
<td>6,605(^*)</td>
</tr>
<tr>
<td>115th</td>
<td>13,556</td>
</tr>
<tr>
<td>114th</td>
<td>12,063</td>
</tr>
<tr>
<td>113th</td>
<td>10,637</td>
</tr>
</tbody>
</table>


\(^*\)Note – 116th Congress data includes all bills and resolutions filed up until July 2, 2019.

“You are at the table or you are on the menu”
How can advocacy help balance the scales?

- Builds relationships
- Establishes credibility
- Protects interests

The examples of advocacy are based on expert opinion and are not directive of engagement in advocacy activities.
What are the issues for patients with chronic inflammatory diseases?

Payer
- Utilization management
- Reimbursement
- Affordability

Policy
- Legislation
- Regulation
- Rules/guidance

Humanistic
- Public/personal
- College/work
- Accommodations
What are the issues for patients with chronic inflammatory diseases?

**Prior Authorization**

66% of rejected prescriptions at the pharmacy require PA\(^1\)

**Step Therapy**

In 2010, nearly 60% of commercial insurers were using step therapy. As of 2013, 75% of large employers reported offering plans that use step therapy\(^2,3\)

**Non-medical Switching**

A Feb. 2019 study on non-medical switching showed two-thirds of chronic disease respondents said the switch impacted their ability to be productive at work, while more than 40% said they weren’t able to care for their children, spouses or other family members as needed\(^4\)

**Out of Pocket**

29% of US patients delayed health care in 2018 because of high patient financial responsibility\(^5\)

---

How has policy helped to address issues for patients with chronic inflammatory diseases?

Step Therapy Laws

Figure 1:

Step Therapy
Non-Medical Switching
Ally’s Law
Co-Pay Surprise

Figure 1: Map created using online state map generator tool. https://mapchart.net/usa.html. Information used to populate the map was obtained from the SAIM Coalition website. https://www.saimcoalition.org/saim-legislation-by-state/. Accessed on July 26, 2019.
What are the issues for patients with chronic inflammatory diseases?

- Work
- College
- Young Adults
- Public
Engaging in advocacy: Examples of provider advocates

**Simple Advocacy**
- Petitions
- Op-Ed
- Online testimony
- Phone, email, and social media outlets
- Action alerts
- Colleagues

**High-Level Advocacy**
- Committee testimony
- Office & facility tours
- Advisory committees
- Advocacy/Hill Day
- Advocacy committees
- Regulatory comments
Engaging in advocacy: Examples for provider advocates to help patients

Resources

Connections

Identification
Recall that Kyra’s insurance provider denied coverage for her prescribed therapy as it is not indicated for the M46.90 diagnostic code selected by her rheumatologist.

Kyra’s rheumatologist requests help from the professional society’s insurance committee.

Professional societies, scientific literature, CDC/NCHS website

Kyra’s rheumatologist joins the professional society’s care and research committees.

Lack of an ICD-10 code

Coverage for the biologic therapy selected by Kyra’s rheumatologist is approved.

The professional society submits public comments supporting the proposed code.

A new ICD-10 code is developed.

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
Recall that Jocelyn is a patient with PSO who develops PsA. Her health plan requires her to “fail first” before approving coverage of a prescribed biologic.

The health plan’s fail-first policy is one-size-fits-all and does not account for complex cases.

Jocelyn shares her experience with her provider and advocacy organization. She is introduced to a coalition working on the issue.

Jocelyn engages with stakeholders on social media.

The coalition develops legislation that accounts for Jocelyn’s experience. The legislation is introduced.

The legislation succeeds and is signed into law.

Jocelyn’s health plan wants her to fail first before approving coverage for the biologic.

Issue-specific coalitions, grassroots mobilization, targeted media

Jocelyn works with a media consultant to publish her experience in key media markets.

Jocelyn participates in a grassroots letter writing campaign.

Patients and providers have streamlined access to appropriate therapies.

Background

Identify the Problem

Resources

Action

Outcome

Action

Action

Outcome

Outcome

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
CD Patient Journey
Tobias, 20 years old, Barista and College Student

Recall that Tobias is a 20-year-old college sophomore with CD. Some settings do not allow for reliable, quick, or private access to a bathroom.

Tobias applies for housing in his college’s dormitory, and requests accommodation.

Tobias’s college turns down his request for accommodation.

Tobias’s college does not understand why his condition necessitates private restroom access.

Both his provider and his advocacy organization send letters to Tobias’s college. Tobias files an appeal.

Patient-provider relationship, advocacy organizations, implementation and compliance education, state oversight bodies

What resources are available?

The advocacy organization educates the university on issues faced by patients with CD with an informational presentation.

Tobias obtains a “restroom access card.”

Tobias gets in touch with his provider and his advocacy organization to convey the issue he is experiencing at his college.

Tobias is granted accommodation.

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
Meera, a woman of childbearing potential, experiences severe disease symptoms and is also a woman of childbearing potential. She and her physician select a therapy that her insurance provider covers. However, her health plan removes the therapy from its formulary in the middle of her plan year. Meera’s health plan can change her coverage while she is locked into her current plan.

Advocacy organizations, lobbyists, in-person advocacy

Legislation becomes law and prevents future non-medical switching.

Meera and her physician select a therapy that her insurance provider covers. However, her health plan removes the therapy from its formulary in the middle of her plan year.

Identify the problem

Formulary changes do not take unique patient needs into account.

Meera shares her story with her provider and advocacy organization, which works to introduce legislation.

Meera’s health plan can change her coverage while she is locked into her current plan.

Action

Action

Action

Outcome

Meera attends an “advocacy day.”

Meera testifies about her experience during a hearing for the bill.

This is a fictional patient journey based on typical experiences in this patient population. There is no implication that the scenarios would change with or without treatment. For illustrative purposes only.
Access for patients can be shaped through advocacy

The future of medicine can be shaped through advocacy

If we’re not at the negotiating table, we leave ourselves and our patients open to unwanted change

As healthcare providers, we have important relationships with local patients who choose legislators, making our real-world input vital to developing proficient legislators

Remember that…
Questions?