BY ELECTRONIC MAIL:

MedicarePhysicianFeeSchedule@cms.hhs.gov

February 10, 2024

The Honorable Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Attention: CMS-1784-F
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Dental Coverage Nomination –Autoimmune Disease Patients on Immunosuppressive Therapy

Dear Administrator Brooks-LaSure:

The Sjögren's Foundation (https://sjogrens.org) is honored to lead the effort along with related autoimmune disease organizations to provide the Centers for Medicare and Medicaid Services (CMS) our nomination requesting coverage of medically necessary dental services for individuals with autoimmune diseases who are initiating or undergoing immunosuppressive or immunomodulator therapy ("immunosuppressive therapy"). We are grateful for the opportunity to submit this nomination again as dental care is an essential component of the medical treatment of persons affected by systemic autoimmune disease. We applaud the Administration for its commitment to engage with the public on ways to strengthen access to medically necessary dental coverage for Medicare beneficiaries.

The Sjögren's Foundation is a 501(c)3 patient advocacy organization that serves as the voice for all Sjögren's patients through advocacy and awareness initiatives; supports Sjögren's patients and their loved ones through education, resources, and services; provides credible resources and education for healthcare professionals; and leads, encourages, and funds innovative research projects to better understand, diagnose, and treat Sjögren's. We are proud to partner with other patient advocacy organizations representing related systemic autoimmune diseases with this nomination and appreciate our and these groups' key medical leaders' continued support.

In its CY2023 Physician Fee Schedule Final Rule, CMS clarified its interpretation of Section 1862(a)(12) of the Social Security Act, resulting in the acknowledgement that Medicare payment can be made in certain clinical scenarios in which dental services are inextricably linked to, and substantially related and integral to the clinical success of, a covered medical service. This will have a significant impact on the lives of thousands of Medicare beneficiaries for whom dental treatment is critical to their medical outcomes.

We seek CMS' recognition that immunosuppressive therapies prescribed to manage autoimmune diseases can be severely complicated and compromised by oral/dental disease and conditions. We respectfully ask CMS to find that medically necessary dental services in these clinical circumstances meet the criteria for which payment may be made.

The bases for our nomination are set forth below, and include **Appendix A**, which lists the **CPT codes** for some exemplary **medical procedures** associated with management of autoimmune diseases, the outcomes for which can be improved by identifying and resolving dental infections. As some of the codes reference specific pharmaceuticals, we have included in **Appendix B** a compilation of exemplary Prescribing Information (PI) which provide cautionary guidance about the increased risk for opportunistic infections and/or spread of existing infections associated with moderate to severe immunosuppressive management of autoimmune diseases.

Clinical Justification: Immunosuppression

In the CY2023 PFS final rule, CMS approved Medicare payment for a dental or oral examination as part of a work-up before covered organ transplantation (including stem-cell and bone marrow transplant) procedures as well as for dental services needed to eradicate infection prior to or contemporaneously with such procedures. A key rationale for allowing such payment was the knowledge of the risks that dental infections pose to transplant patients who are prescribed immunosuppressant therapies to prevent organ transplant rejection.

In the CY2024 PFS final rule, CMS approved payment for dental services to diagnose and address oral infections that could complicate certain treatments for cancer patients. Chemotherapy and CAR T-Cell therapies were specifically identified, as these treatments induce immunosuppression, impairing the cells of a cancer patient's immune system and reducing their ability to fight infections and other disease. Compelling to the Agency was the fact that if dental or oral infections are left undetected or untreated in this population, serious complications may occur and negatively impact the course and outcome of the covered cancer treatment for the patient.

There is notable overlap in the pharmaceuticals prescribed for autoimmune disease patients undergoing immunosuppressive therapy and individuals undergoing organ transplantation (e.g., Imuran and Cellcept) as well as individuals receiving cancer chemotherapies (e.g., Cytoxan and Methotrexate). As noted, for example in **Appendix B**, methotrexate may be used as part of a cancer chemotherapy regimen as well as for the treatment of rheumatoid arthritis (RA).

The intensity of immunosuppression from those pharmaceuticals and other related drugs is dose and duration dependent. Higher dosing is used for cancer chemotherapy and organ transplant rejection prevention. However, the duration of use is generally much shorter than when used in autoimmune disease therapy. Indeed, the longer-term duration of use for managing symptoms of autoimmune disease can expose patients to ongoing serious risk of complicating infections for decades.[1,2]

Immunosuppression is a broadly shared condition by individuals with autoimmune disease since many require disease-modifying drugs to manage symptoms. Pharmaceuticals generally include guidance about the heightened risk of infection-related complications when on immunosuppressive therapies. **Appendix B** provides further excerpts from Prescribing Information (PI) for exemplary immunosuppressive/immunomodulating pharmaceuticals used to manage various autoimmune diseases.

National medical specialty organizations, such as the American Academy of Neurology, note that patients undergoing immunosuppressive therapy are highly susceptible to very serious infections which can result simply from poor dentition. The American College of Rheumatology states it is vital for patients to receive appropriate dental evaluation and prompt treatment so they can continue their immune suppressant medications.

Complications relating to dental infections and immunosuppressive therapies

Dental infections can spread more easily, and therefore faster, when host immunity is compromised by immunosuppressing/immunomodulating drugs. There are three possible pathways for the bacteria to spread: locally through facial spaces, through the blood stream, and by aspiration.

A. Cellulitis, Ludwig's angina, dissecting facial space abscesses

Untreated dental infections can dissect beyond the teeth and supporting tissues to involve sinuses, the eye, brain, and neck. Severe swelling associated with Ludwigs's angina can create

[1] "The heightened risk of infection in autoimmune disease is compounded by immunosuppressive therapies with prolonged duration of effect (eg, rituximab, tocilizumab)." Immunosuppressive Agents and Infectious Risk in Transplantation: Managing The Net State of Immunosuppression, Matthew B Roberts, Jay A Fishman, Clinical Infectious Diseases, Volume 73, Issue 7, 1 October 2021, https://doi.org/10.1093/cid/ciaa1189

[2] "Risk of infection in neutropenic patients is associated with both the severity and duration of neutropenia." Fish D. and Mueller S., Infections in Immunocompromised Patients. Basicmedical Key; Infections in Immunocompromised Patients | Basicmedical Key

airway obstruction. Risk factors for increased morality and complications include being aged 65 and older and immunosuppression, among other conditions.[3] The pathological process of dissection can develop faster and progress more aggressively when individuals are immunocompromised. This can be the case for those who are prescribed immunosuppressive drugs to effectively manage their autoimmune diseases.

B. Blood stream infections (BSIs) that can spawn sepsis

Bacterial pathogens responsible for odontogenic infections can gain access to the blood stream and, in turn, trigger sepsis -- a life threatening organ failure caused by a dysregulated host response to infection. Individuals who are immunocompromised as a result of medical conditions or medications that interfere with normal immune function are considered to be at particularly high risk for developing and potentially dying of sepsis.[4],[5] CMS noted in the CY2024 PFS final rule that proceeding without a dental or oral exam of the mouth prior to chemotherapy could lead to systemic infection or sepsis, among other complications. Similar outcomes can follow for those receiving immunosuppressive therapy to treat autoimmune diseases.

C. Recurrent Pneumonias and Other Respiratory Conditions

The oral cavity is a known reservoir for pulmonary infections. Aspirating dentally-sourced microorganisms does not often cause disease in healthy people, but can present serious respiratory risks for individuals undergoing immunosuppressant therapy, and lead to greater health complications.[6] Without resolving the oral reservoir of associated microbes prior to such therapy, recurrent and increasingly serious complications can develop in individuals with autoimmune diseases.

It stands to reason that the combination of virulent progressive bacterial infections, including from dental sources, and sustained long-term immunosuppression from disease or covered pharmaceutical prescribing, creates consequential risk for complications. Accordingly, it is broadly understood in such circumstances that reducing the risk by resolving infections and, ideally preventing them, is widely accepted standard practice. That is the basis, along with results from extensive clinical trials, for standard warnings in prescribing information for many immunosuppressive and immunomodulating pharmaceuticals regarding related infection risks.

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[3] An J, Madeo J, Singhal M. Ludwig Angina. [Updated 2023 May 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK482354/

[4]Poutsiaka DD, Davidson LE, Kahn KL, Bates DW, Snydman DR, Hibberd PL. Risk factors for death after sepsis in patients immunosuppressed before the onset of sepsis. *Scand J Infect Dis.* 2009;41:469–479.

[5] Tolsma V, Schwebel C, Azoulay E, Darmon M, Souweine B, Vesin A, et al. Sepsis severe or septic shock: outcome according to immune status and immunodeficiency profile. *Chest.* 2014;146:1205–1213.

[6] Pulmonary Embolism (PE) - Lung and Airway Disorders - Merck Manuals Consumer Version. https://www.merckmanuals.com/home/lung-and-airway-disorders/pulmonary-embolism/pulmonary-embolism-pe

The described complications lower an individual's quality of life and could hamper their ability to proceed with the immunosuppressive therapy or prevent its successful outcome. The American College of Physicians notes that the implications of dental disease in patients who are undergoing immunosuppressive therapy extend beyond their oral disease, with potentially life-threatening complications if the dental problems are not treated. This underscores our recommendation that this covered service should not proceed until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection.

Additional Complication: Oral Mucositis

As noted in the CY2024 PFS final rule, immunosuppression induced by chemotherapy in the treatment of cancer increases the likelihood and intensity of complications for the patient that could potentially impact the ability to complete the totality of the treatment. This is further supported by data that showed a possible increased incidence of oral mucositis when dental treatment is not administered at least 2-3 weeks prior to the initiation of cancer treatment.[7]

Chemotherapy regimens containing methotrexate are associated with increased risk of mucositis[8], and studies have shown increased risk for oral mucositis when using methotrexate for RA[9]. In the CY2024 final rule, AHRQ found similar evidence to support that dental evaluation/treatment prior to cancer treatment led to decreased incidence and/or less severity of serious oral infections and complications like oral mucositis. We encourage CMS to explore this connection to confirm that dental evaluations and treatment prior to immunosuppressive therapy would lead to decreased incidence of serious oral infections.

Additional Considerations in Patients with Autoimmune Diseases

Several reasons support the premise that dental care is critical to good medical care in autoimmune disease. First, persons with specific forms of systemic autoimmune disease are at much higher risk of advanced dental decay, dental loss, and/or gum disease.[10] Factors that contribute to this increased risk include inadequate secretion of saliva, difficulties with routine oral hygiene due to a narrowed oral aperture, gastroesophageal reflux, and direct effects of medications, such as immunosuppressants. We believe it is critical that beneficiaries with an autoimmune disease that requires immunosuppressive therapy have access to necessary dental services, as proper dental care for this population can reduce the incidence of serious infection and improve overall patient outcomes for the covered service. Of note, immunosuppressive therapies used in one autoimmune disease are often used off-label for other, related autoimmune

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[7] Thais Mazzetti, Paulo Sergio da Silva Santos, Héliton Spindola Antunes, Anelise Fernandes Montagner, Françoise Hélène van de Sande, Tamires Timm Maske, Required time for pre-oncological dental management – A rapid review of the literature, Oral Oncology, Volume 134, 2022, https://doi.org/10.1016/j.oraloncology.2022.106116.

[8] Management of Cancer Therapy-Associated Oral Mucositis. JCO Oncology Practice. Volume 16, Number 3. February 03, 2020. https://doi.org/10.1200/JOP.19.0065

[9] Oral mucositis in patients receiving low-dose methotrexate therapy for rheumatoid arthritis: report of 2 cases and literature review. Oral Medicine. Volume 115, Issue 5 E28-E33. May 2013. https://doi.org/10.1016/j.oooo.2012.12.008

[10] Nair, Soumya et al. "Role of autoimmune responses in periodontal disease." *Autoimmune Diseases,* vol. 2014 (2014): 596824. doi:10.1155/2014/596824

diseases. For example, providers prescribe rituximab and belimumab off-label in Sjögren's patients for whom other therapies are insufficient. This opportunity to expand coverage is important as new immunosuppressive and immunomodulator drugs will be coming onto the market for autoimmune diseases, and dental coverage will be integral to the success of those products.

As Dr. Richard M. Silver and Dr. Jessica K. Gordon aptly wrote on behalf of the Scleroderma Foundation (see **Appendix C**):

> "[A] mainstay of prevention of dental complications in scleroderma is dental hygiene which needs to be accomplished by dentists and hygienists due to restriction in hand mobility in scleroderma patients. As such, the need for expansion of dental services under Medicare Parts A and B for this patient population is paramount."

Autoimmune disease patients initiating or undergoing immunosuppressive therapy may have particular clinical issues that warrant consideration by CMS. Another such issue is temporomandibular joint (TMJ) pain, which can affect one's ability to chew, and tends to occur in individuals who have scleroderma, Sjögren's, lupus, and RA. Patients taking immunosuppressants experience more TMJ impairment and a possible increased risk of oral and other cancers.[11] Notably, while a mainstay of RA treatment, use of TNF-alpha therapies are discouraged for use in Sjögren's patients, unless those patients also have RA or RA features, because of a potential for increased risk of lymphoma development in those with Sjögren's.[12] Autoimmune patients already are at increased risk of developing cancers, with Sjögren's, among all autoimmune diseases, having the highest risk of lymphoma and other cancers.[13]

Stakeholder Support for the Nomination

There is unanimous guidance from relevant medical specialty organizations that chronic progressive dental infections in the presence of immunosuppression creates the risk of adverse medical complications that can require disruption or discontinuation of pharmacological management controlling symptoms of autoimmune diseases.

> "Given the broad array of neurological diseases that are affected by poor dentition, as well as the many neurological conditions that require immunosuppressive therapy, access to good dental care is essential to our patients."
>
> *American Academy of Neurology*

[11] Hirai, Hideai, et. al. "Clinical Course of Oral Squamous Cell Carcinoma in Patients on Immunosuppressant and Glucocorticoid Therapy." Journal of Oral and Maxillofacial Surgery, vol. 75, no. 9, 2017, pp. 1980-1986, https://www.joms.org/article/S0278-2391(17)30075-7/fulltext#%20.

[12] Carsons, Steven E et al. "Treatment Guidelines for Rheumatologic Manifestations of Sjögren's Syndrome: Use of Biologic Agents, Management of Fatigue, and Inflammatory Musculoskeletal Pain." *Arthritis Care & Research,* vol. 69,4 (2017): 517-527. doi:10.1002/acr.22968

[13] Mackay, I R, and N R Rose. "Autoimmunity and lymphoma: tribulations of B cells." *Nature Immunology,* vol. 2,9 (2001): 793-5. doi:10.1038/ni0901-793

"Dental problems, particularly dental infections, pose a major problem for patients with cardiac valvular disease, patients who are immunosuppressed by virtue of underlying disease or immunosuppressive medications, patients with various types of prostheses, and patients who are at risk of aspiration. The implications of dental disease in such patients extend well beyond their oral disease, with potentially life-threatening complications if the dental problems are not treated."

American College of Physicians

"Many of our patients take medications that suppress their immune systems to control their rheumatologic disease. The combination of the secondary health issues along with potential side effects from the medication increase the likelihood of dental problems. It is vital for patients to receive appropriate dental evaluation and prompt treatment so they can continue their immune suppressant medications.."

American College of Rheumatology

"Dental and respiratory health are interrelated. Bacterial biofilms between teeth harbor pathogens that, when aspirated, can increase susceptibility or complicate the management of pulmonary diseases such as pneumonia, bronchitis, and chronic obstructive pulmonary disease (COPD). The risk is greater in immune-compromised individuals."

American Thoracic Society

"Older adults with poor oral health are at increased risk for aspiration pneumonia, poorly controlled diabetes, endocarditis, and inadequate nutrition, among other systemic health problems. Many are immunocompromised by illnesses or medication used to treat cancers and autoimmune diseases, increasing the risk that dental infections can spread."

The Gerontological Society of America

Leading Organizations for this nomination are also clear about the importance of the action being requested of the Agency. Indeed, we are proud the following leaders are in support of this nomination:

- Arthritis Foundation
- Autoimmune Association
- Crohn's and Colitis Foundation
- International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
- Lupus and Allied Diseases Association, Inc.
- Lupus Foundation of America
- National Multiple Sclerosis Society
- National Scleroderma Foundation

Thus, physicians across the medical specialties involved in treating autoimmune diseases acknowledge that treatment to resolve dental infections can be integral to improving outcomes among patients requiring use of immunosuppressive medications.

In addition, this nomination has been endorsed by the more than 240 organizations that make up the Consortium for Medically Necessary Oral Health Coverage (Consortium). A leading voice for Medicare payment clarification for medically necessary oral and dental services that are inextricably linked, essential, and of profound clinical, fiscal, and human value to Medicare beneficiaries, the Consortium recognizes that overall health is inextricably linked to oral health. Regrettably, dental care has long been inaccessible to millions of Medicare beneficiaries, leading to an alarming situation in which two-thirds of older Americans have periodontal disease and one-fifth have lost all of their teeth. Untreated oral conditions also significantly increase Medicare beneficiaries' risk of suffering chronic conditions, resulting in impaired well-being, increased hospitalizations, and higher program costs.

In support of transformative change, the Consortium has urged Congress and the Administration to explore options for extending access to evidence-based treatment to all Medicare beneficiaries. Consortium members include the leading organizations listed at www.HealthCareConsortium.org.

Closing & Recommendation

As noted in the CY2024 PFS final rule, CMS recognized payment for certain dental services that serve to mitigate the likelihood of occurrence and severity of complications caused by primary medical services. Such dental services also facilitate the successful completion of the prescribed course of treatment, and thus are integral and inextricably linked to these medical services. We believe CMS should extend this dental payment to autoimmune disease patients receiving immunosuppressive therapy, as it would substantially transform treatment and outcomes for this modest, yet highly impacted, population.

Autoimmune disease patients are already at a heightened risk of oral complications and a variety of other health consequences. This clinical scenario would capture a subset of this population that are utilizing immunosuppressive therapy, a covered service, and provide a pathway for which payment can be made for certain dental services that would ensure the appropriate initiation and facilitate optimal results from the prescribed immunosuppressive therapy.

We urge CMS to consider extending Medicare dental payment for autoimmune disease patients undergoing immunosuppressive or immunomodulator therapy. Access to proper dental care for this population is critical to the success of their treatment. Thank you for your consideration of this nomination. For additional information, please contact Katherine M. Hammitt, MA, Vice President of Medical and Scientific Affairs at the Sjögren's Foundation, at khammitt@sjogrens.org.

Sincerely,

Janet E Church
President & Chief Executive Officer
Sjögren's Foundation

Autoimmune Disease Patient Advocacy Groups represented on this proposal:

Arthritis Foundation
Autoimmune Association
Crohn's and Colitis Foundation
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
National Multiple Sclerosis Society
National Scleroderma Foundation

Appendix A

Medical Services for which identification and resolution of dental infections can be inextricably linked to improved outcomes

Medical treatment for diseases requiring therapeutic immunosuppression when dental infections risk/cause blood stream infections, sepsis.

CPT codes 99212-99215: Evaluation and Management (E/M) Services
CPT codes 96365-96368: Infusion services
CPT codes for immunosuppressant drugs, such as:

- J0129: Abatacept (Orencia) for Rheumatoid Arthritis
- J0135: Adalimumad (Humira) for Crohn's, Ulcerative Colitis, Rheumatoid Arthritis
- J0490: Belimumab (Benlysta) for systemic lupus erythematosus (SLE), Lupus Nephritis, and Sjögren's
- J0491: Anifrolumab-fnia (Saphnelo) for systemic lupus erythematosus (SLE)
- J1303: Ravulizumab-cwvz (Ultomiris) for Generalized Myasthenia Gravis
- J1438: Etanercept (Enbrel) for Rheumatoid Arthritis, Ankylosing Spondylitis
- J1595: Glatiramer (Copaxone) for Multiple Sclerosis
- J1602: Golimumab (Simponi) for Rheumatoid Arthritis, UC, Ankylosing Spondylitis
- J1745: Infliximab (Remicade) for Crohn's, Ulcerative Colitis, Rheumatoid Arthritis
- J2250: Upadacitinib (Rinvoq) for Rheumatoid Arthritis, Ulcerative Colitis, Crohn's
- J2323: Natalizumab (Tysabri) for Multiple Sclerosis
- J2350: Ocrelizumab (Ocrevus) for Multiple Sclerosis
- J3262: Tocilizumab (Actemra) for Scleroderma-associated lung fibrosis
- J3357: Ustekinumab (Stelara) for Crohn's, Ulcerative Colitis, Psoriatic Arthritis
- J3380: Vedolizumab (Entyvio) for Crohn's, Ulcerative Colitis
- J3590: Secukinumab (Cosentyx) for Plaque Psoriasis
- J7500: Azathioprine (Imuran) for Lupus, Crohn's, Sjögren's
- J7517: Mycophenolate (Cellcept) for Lupus, Sjögren's
- J9070: Cyclophosphamide (Cytoxan) for Sjögren's, Vasculitis
- J9250: Methotrexate for Sjögren's, Rheumatoid Arthritis (unresponsive to other treatment)
- J9302: Ofatumumab (Kesimpta) for Multiple Sclerosis
- J9312: Rituximab (Rituxan) for Rheumatoid Arthritis, Sjögren's
- J9332: Efgartigimod (Vyvgart) for Myasthenia Gravis

Medical treatment for pulmonary diseases when aspiration of dental pathogens risk/cause the initiation and/or recurrence of complications.

CPT codes 99212-99215: Evaluation and Management (E/M) Services
CPT code 99291: Critical Care Services
DRG code 177: Hospitalization for respiratory infections and inflammation
DRG code 190: COPD with complications

Medical treatment for dentally-sourced dissecting maxillofacial space infections:

CPT 41000: Intraoral incision and drainage of abscess
CPT 87181: Antibiotic susceptibility study
CPT 96365: Infusion of antibiotic
CPT codes 99281-99285: Emergency department services
CPT codes 99291-99292: Critical care services
DRG code 135: Sinus procedures with CC/MCC
DRG code 141: Major head and neck procedures with CC
DRG code 872: Hospitalization for septicemia or severe sepsis

Appendix B

Excerpts from Prescribing Information

Note: The **"Warning and Precautions**" sections below all cite the risk of infection related to the use of biologics and other immunosuppressing/immunomodulating pharmaceuticals to manage symptoms of autoimmune diseases. The information is the result of extensive and rigorous clinical trials conducted by pharmaceutical companies and approved by the FDA. Mention is not made of specific opportunistic infections that can develop, or exacerbation/spread of specific existing infections. It is axiomatic, however, that all infections, regardless of site, risk complications that can compromise the benefits from use of the drugs, prompting delays, disruptions, and discontinuation of use. And the medical specialty organizations noted in this nomination have affirmed that dental infections pose such risks.

ORENCIA

INDICATIONS AND USAGE

Indicated for: • the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA). (1.1) • the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA). (1.2) • the treatment of patients 2 years of age and older with active psoriatic arthritis (PsA). (1.3)

WARNINGS AND PRECAUTIONS

Serious infections reported. Patients with a history of recurrent infections or underlying conditions predisposing to infections may experience more infections. Discontinue if a serious infection develops. (5.3)

HUMIRA

INDICATIONS AND USAGE

Rheumatoid Arthritis (RA) (1.1): reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. • Juvenile Idiopathic Arthritis (JIA) (1.2): reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older. • Psoriatic Arthritis (PsA) (1.3): reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA. • Ankylosing Spondylitis (AS) (1.4): reducing signs and symptoms in adult patients with active AS. • Crohn's Disease (CD) (1.5): treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older. • Ulcerative Colitis (UC) (1.6): treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. Limitations of Use: Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers. • Plaque Psoriasis (Ps) (1.7): treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for

systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

WARNINGS AND PRECAUTIONS
Serious infections: Do not start HUMIRA during an active infection. If an infection develops, monitor carefully, and stop HUMIRA if infection becomes serious. (5.1)

BENLYSTA
INDICATIONS AND USAGE
indicated for the treatment of: • patients aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy; (1) • patients aged 5 years and older with active lupus nephritis who are receiving standard therapy.

WARNINGS AND PRECAUTIONS
Serious Infections: Serious and sometimes fatal infections have occurred in patients receiving immunosuppressive agents, including BENLYSTA. Use with caution in patients with severe or chronic infections. Consider interrupting therapy with BENLYSTA if patients develop a new infection during treatment with BENLYSTA.

SAPHNELO
INDICATIONS AND USAGE
Indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy. (1)

WARNINGS AND PRECAUTIONS
Serious Infections: Serious and sometimes fatal infections have occurred in patients receiving SAPHNELO. SAPHNELO increases the risk of respiratory infections and herpes zoster. Avoid initiating treatment during an active infection. Consider the individual benefit-risk if using in patients with severe or chronic infection ns. Consider interrupting therapy with SAPHNELO if patients develop a new infection during treatment.

ULTOMIRIS
INDICATIONS AND USAGE
Indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive (1.3)

WARNINGS AND PRECAUTIONS
Other Infections: Use caution when administering ULTOMIRIS to patients with any other systemic infection (contraindicated for patients with unresolved Neisseria meningitidis infection)

ENBREL

INDICATIONS AND USAGE

Indicated for the treatment of: Adult patients with: • Rheumatoid Arthritis (RA) (1.1) • Psoriatic Arthritis (PsA) (1.3) • Ankylosing Spondylitis (AS) (1.4) • Plaque Psoriasis (PsO) (1.5)

WARNINGS AND PRECAUTIONS

Do not start Enbrel during an active infection. If an infection develops, monitor carefully and stop Enbrel if infection becomes serious. (5.1)

COPAXONE

INDICATIONS AND USAGE

Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults (1).

WARNINGS AND PRECAUTIONS

Because COPAXONE can modify immune response, it may interfere with immune functions.

SIMPONI

INDICATIONS AND USAGE

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

WARNINGS AND PRECAUTIONS

Serious Infections: Do not start SIMPONI ARIA during an active infection. If an infection develops, monitor carefully, and stop SIMPONI ARIA if infection becomes serious

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REMICADE

INDICATIONS AND USAGE

Indicated for: • Crohn's Disease: ° reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. (1.1) • Pediatric Crohn's Disease: reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy. (1.2) • Ulcerative Colitis: reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to

conventional therapy. (1.3) Rheumatoid Arthritis in combination with methotrexate: reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active disease. (1.5) • Ankylosing Spondylitis: reducing signs and symptoms in adult patients with active disease. (1.6) • Psoriatic Arthritis: reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients. (1.7) • Plaque Psoriasis: treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. (1.8)

WARNINGS AND PRECAUTIONS
Serious infections – do not give REMICADE during an active infection. If an infection develops, monitor carefully and stop REMICADE if infection becomes serious. (5.1)

RINVOQ
INDICATIONS AND USAGE
Indicated for the treatment of: • Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers • Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. (1.2)• Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. (1.3) • Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. (1.4) • Adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers. (1.5) • Adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. (1.6) • Adults with active non-radiographic axial spondylarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. (1.7)

WARNINGS AND PRECAUTIONS
Serious Infections: Avoid use in patients with active, serious infection,\

TYSABRI
INDICATIONS AND USAGE
Indicated for treatment of: Multiple Sclerosis (MS) TYSABRI is indicated as monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. TYSABRI increases the risk of PML [See Warnings and Precautions (5.1)]. When initiating and continuing

treatment with TYSABRI, physicians should consider whether the expected benefit of TYSABRI is sufficient to offset this risk. (1.1) Crohn's Disease (CD) • TYSABRI is indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-α. (1.2)

WARNINGS AND PRECAUTIONS
Immunosuppression/Infections: TYSABRI may increase the risk for certain infections. Monitor patients for development of infections due to increased risk with use of TYSABRI (5.6)

OCREVUS
INDICATIONS AND USAGE
Indicated for the treatment of: Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults (1) • Primary progressive MS, in adults.

WARNINGS AND PRECAUTIONS
Infections: Delay OCREVUS administration in patients with an active infection until the infection is resolved. Vaccination with live-attenuated or live vaccines is not recommended during treatment with OCREVUS and after discontinuation, until B-cell repletion

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ACTEMRA
INDICATIONS AND USAGE
Indicated for treatment of 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). Giant Cell Arteritis (GCA) (1.2) • Adult patients with giant cell arteritis. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) (1.3) • Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)

WARNINGS AND PRECAUTIONS
Serious Infections – do not administer ACTEMRA during an active infection, including localized infections. If a serious infection develops, interrupt ACTEMRA until the infection is controlled.

STELARA
INDICATIONS AND USAGE
Indicated for the treatment of: Adult patients with: • moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy. (1.1) • active psoriatic arthritis (PsA).

(1.2) • moderately to severely active Crohn's disease (CD). (1.3) • moderately to severely active ulcerative colitis.

WARNINGS AND PRECAUTIONS
Infections: Serious infections have occurred. Do not start STELARA® during any clinically important active infection. If a serious infection or clinically significant infection develops, consider discontinuing STELARA® until the infection resolves.

ENTYVIO
INDICATIONS AND USAGE
Indicated in adults for the treatment of: • moderately to severely active ulcerative colitis (UC). • moderately to severely active Crohn's disease (CD).

WARNINGS AND PRECAUTIONS
Patients treated with ENTYVIO are at increased risk for developing infections. Not recommended in patients with active, severe infections until the infections are controlled. Consider withholding treatment in patients who develop a severe infection

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COSENTYX
INDICATIONS AND USAGE
Indicated for the treatment of: • moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy. (1.1) • active psoriatic arthritis (PsA) in patients 2 years of age and older. (1.2) • adults with active ankylosing spondylitis (AS). (1.3)

WARNINGS AND PRECAUTIONS
Infections: Serious infections have occurred. Exercise caution when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection. If a serious infection develops, discontinue COSENTYX until the infection resolves. (5.1)

IMURAN
INDICATIONS AND USAGE
IMURAN is indicated as an adjunct for the prevention of rejection in renal homotransplantation. It is also indicated for the management of active rheumatoid arthritis to reduce signs and symptoms.

WARNINGS AND PRECAUTIONS
Serious infections. Patients receiving immunosuppressants, including Imuran, are at increased risk for bacterial, viral, fungal, protozoal, and opportunistic infections, including reactivation of latent infections. These infections may lead to serious, including fatal outcomes.

CELLCEPT

INDICATIONS AND USAGE

Indicated for the prophylaxis of organ rejection. CellCept is sometimes prescribed off-label to treat lupus, especially in cases of lupus nephritis.

WARNINGS AND PRECAUTIONS

Increased risk of getting serious infections. CellCept weakens the body's immune system and affects your ability to fight infections.

CYTOXAN

INDICATIONS AND USAGE

Malignant diseases. Cytoxan is sometimes prescribed off-label to manage serious symptoms of Sjögren's, Vasculitis

WARNINGS AND PRECAUTIONS

Myelosuppression, Immunosuppression, Bone Marrow Failure and Infections – Severe immunosuppression may lead to serious and sometimes fatal infections. Close hematological monitoring is required.

METHOTREXATE

INDICATIONS AND USAGE

Indicated for the: • Treatment of adults and pediatric patients with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen (1.1) • Treatment of adults with rheumatoid arthritis (1.2) • Treatment of pediatric patients with polyarticular juvenile idiopathic arthritis (pJIA) (1.3) • Treatment of adults with severe psoriasis (1.4)

PRECAUTIONS

Serious Infections: Monitor patients for infection during and after treatment with Methotrexate Tablets. Withhold or discontinue Methotrexate Tablets for serious infections as appropriate.

KESIMPTA

INDICATIONS AND USAGE

Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

WARNINGS AND PRECAUTIONS

Infections: Delay KESIMPTA administration in patients with an active infection until the infection is resolved.

RITUXAN

INDICATIONS AND USAGE

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).

WARNINGS AND PRECAUTIONS

Infections: Withhold RITUXAN and institute appropriate anti-infective therapy (5.6)

VYVGART

INDICATIONS AND USAGE

Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

WARNINGS AND PRECAUTIONS

Infections: Delay administration of VYVGART to patients with an active infection. Monitor for signs and symptoms of infection in patients treated with VYVGART. If serious infection occurs, administer appropriate treatment and consider withholding VYVGART until the infection has resolved. (5.1)

Appendix C

Submission by the National Scleroderma Foundation

National Scleroderma Foundation

February 10, 2024

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
P.O. Box 8016
Baltimore, MD 21244-8016

The National Scleroderma Foundation represents more than 300,000 people in the US impacted by scleroderma, including those living with the disease, their families and support networks, as well as healthcare providers and investigators. The Foundation is pleased to join with the Sjögren's Foundation and other interested parties in petitioning the Centers for Medicare & Medicaid Services (CMS) to revise the now restrictive definition of medically necessary dental coverage provided under Medicare Parts A and B Payment for Dental (Section II.L.).

Scleroderma is an autoimmune connective tissue disease affecting men, women, and children. People with scleroderma face unique challenges while trying to maintain their oral health. People with scleroderma are more likely to have dental conditions such as small mouth, dry mouth, periodontal disease, and temporomandibular joint disease. Many patients with scleroderma have hand involvement that negatively impacts proper dental hygiene. Additionally, gastroesophageal reflux, nutritional issues, and medications to treat scleroderma may impact the oral mucosa.

The combination of these conditions in individuals with scleroderma leads to dental caries, tooth mobility and loss of teeth. There can be resorption of bone in the jaw which can predispose to fracture of the jaw or teeth. Many individuals with scleroderma have tooth resorption (the patient's cells erode the roots of the teeth) resulting in tooth loss. There is high risk for periodontal infection and increased need for dental surgeries to address this. Additionally, a mainstay of prevention of dental complications in scleroderma is dental hygiene which needs to be accomplished by dentists and hygienists due to restriction in hand mobility in scleroderma patients. As such, the need for expansion of dental services under Medicare Parts A and B for this patient population is paramount.

On behalf of the Medical & Scientific Advisory Board of the National Scleroderma Foundation, we welcome this opportunity to petition for the expansion of access to oral and dental care for vulnerable patient populations including those with systemic sclerosis, in alignment with the Biden-Harris Administration's commitment "to expand access to vital prevention and treatment services."

Richard M. Silver, M.D., M.A.C.R.

Jessica K. Gordon, M.D., MSc

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300 Rosewood Drive, Suite 105
Danvers, MA 01923

scleroderma.org

(800) 722-4673