Monday, October 25, 2021
COVID-19 Email Update
From Dr. Sara Knutson

1) **New FDA/CDC booster recommendations:**

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines

In short, the FDA is amending, and the CDC has approved, the emergency use authorizations (EUA) for COVID-19 vaccines to allow for the use of a single booster dose as follows:

The use of a single booster dose of the Moderna COVID-19 Vaccine that may be administered at least 6 months after completion of the primary series to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2 The use of a single booster dose of the Janssen (Johnson and Johnson)

COVID-19 Vaccine may be administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older.

The use of each of the available COVID-19 vaccines as a heterologous (or "mix and match") booster dose in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine.

A single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered at least 6 months after completion of the primary series to individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.

2) **Please make sure patients you refer for monoclonal AB are consented and ready to proceed.** Last minute disruptions in this are troublesome to an overburdened nursing staff and compromise other patients' access to available appointments. We are scheduling 20-22 patients/week at this point, so the schedule can get a little tight. It is best to refer your patients earlier in the week if possible. Montrose County (970-240-7194) and Mesa County (970-858-2119) patients should be referred to their counties via the phone numbers provided rather than entered into our allocation system. Do not enter your patients as 'post exposure prophylaxis' unless they are COVID negative and meet the PEP criteria. Please call if you have any questions.

3) There are **new guidelines for vaccine administration among patients receiving rheumatologic medications**, such as MTX, leflunamide, MMF, AZA etc). These are nicely summarized in the attached ACR statements In short, you need to pay attention to several areas here:

   - What to do with rheum meds when a patient is infected with COVID or exposed to COVID (often these meds are held and resumed after a negative test or at 2 weeks after exposure)

   - What to do with the timing of rheum meds and vaccines/boosters (often these meds are held until 1-4 weeks after a vaccine to avoid compromising vaccine efficacy)

   - Consider referral of your patients with COVID infection and/or significant exposure for monoclonal AB. (These patients are at especially high risk for more severe disease.)

4) Efficacy of the Pfizer 3rd dose booster against symptomatic infection was reported at 96.5% in a recent Phase 3 trial. See attachment for details. Most of us as HCPS are far enough out from the original Pfizer 2 dose series that immunity may have waned and you no longer have full protection. Please consider getting your booster! (Notably, this same study found side effects after the booster dose were milder than after dose 1 or 2).

Dr. Sara Knutson, M.D.
Board Certified
Pulmonology/Critical Care

Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID-19 Vaccine

October 21, 2021

- *First results from any randomized, controlled COVID-19 vaccine booster trial demonstrate a relative vaccine efficacy of 95.6% against disease during a period when Delta was the prevalent strain*
- *In trial with more than 10,000 participants 16 years of age and older, COVID-19 booster was found to have a favorable safety profile*
- *Companies plan to submit these data to FDA, EMA and other regulatory agencies to further support licensure in the U.S. and other countries*

NEW YORK and MAINZ, GERMANY, October 21, 2021 —Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced topline results from a Phase 3 randomized, controlled trial evaluating the efficacy and safety of a 30-µg booster dose of the Pfizer-BioNTech COVID-19 Vaccine in more than 10,000 individuals 16 years of age and older. In the trial, a booster dose administered to individuals who previously received the Pfizer-BioNTech primary two-dose series restored vaccine protection against COVID-19 to the high levels achieved after the second dose, showing a relative vaccine efficacy of 95.6% when compared to those who did not receive a booster. These are the first efficacy results from any randomized, controlled COVID-19 vaccine booster trial.

"These results provide further evidence of the benefits of boosters as we aim to keep people well-protected against this disease," said **Albert Bourla, Chairman and Chief Executive Officer, Pfizer**. "In addition to our efforts to increase global access and uptake among the unvaccinated, we believe boosters have a critical role to play in addressing the ongoing public health threat of this pandemic. We look forward to sharing these data with health authorities and working together to determine how they can be used to support the rollout of booster doses around the world."

"These important data add to the body of evidence suggesting that a booster dose of our vaccine can help protect a broad population of people from this virus and its variants," said **Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. "Based on these findings we believe that, in addition to broad global access to vaccines for everyone, booster vaccinations could play an important role in sustaining pandemic containment and a return to normalcy."

All trial participants previously completed the primary two-dose series of the Pfizer-BioNTech vaccine, and then were randomized 1:1 to receive either a 30-µg booster dose (the same dosage strength as those in the primary series) or placebo. The median time between second dose and administration of the booster dose or placebo was approximately 11 months. Symptomatic COVID-19 occurrence was measured from at least 7 days after booster or placebo, with a median follow-up of 2.5 months. During the study period, there were 5 cases of COVID-19 in the boosted group, and 109 cases in the non-boosted group. The observed relative vaccine efficacy of 95.6% (95% CI: 89.3, 98.6) reflects the reduction in disease occurrence in the boosted group versus the non-boosted group in those without evidence of prior SARS-CoV-2 infection. Median age of participants was 53 years, with 55.5% of participants between 16 and 55 years, and 23.3% of participants 65 years and older. Multiple subgroup analyses showed efficacy was consistent irrespective of age, sex, race, ethnicity, or comorbid conditions.

The adverse event profile was generally consistent with other clinical safety data for the vaccine, with no safety concerns identified.

Pfizer and BioNTech plan to submit detailed results from the trial for peer-reviewed publication. The companies also plan to share these data with the U.S. Food and Drug Administration, European Medicines Agency, and other regulatory agencies around the world as soon as possible.

On September 22, 2021, a booster dose of the Pfizer-BioNTech COVID-19 Vaccine was authorized for emergency use by the U.S. FDA for individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2. On October 20, 2021, a booster dose of the vaccine also was authorized for emergency use by the U.S. FDA in eligible individuals who have completed a primary vaccination with a different authorized COVID-19 vaccine. In addition, a booster dose of the vaccine is authorized in the European Union and other countries, with recommendations for populations varying based on local health authority guidance.

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder in the United States, the European Union, the United Kingdom, Canada and the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries. Submissions to pursue regulatory approvals in those countries where emergency use authorizations or equivalent were initially granted are planned.

U.S. Indication & Authorized Use
HOW IS THE VACCINE GIVEN?
The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:

- A single booster dose of the vaccine may be administered to individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

- A single booster dose may be administered to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.

WHAT IS THE INDICATION AND AUTHORIZED USE?
The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably. Although they may be manufactured in different facilities, the products offer the same safety and effectiveness.

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.

- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older.
- It is also authorized under EUA to be administered to provide:
    - a two-dose primary series in individuals 12 through 15 years;
    - a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
    - a single booster dose in individuals:
        - 65 years of age and older
        - 18 through 64 years of age at high risk of severe COVID-19
        - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

- a two-dose primary series in individuals 12 years of age and older;
- a third primary series dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose in individuals:
    - 65 years of age and older
    - 18 through 64 years of age at high risk of severe COVID-19
    - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.

EUA Statement
Emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 12 years of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see EUA Fact Sheet at www.cvdvaccine-us.com.

IMPORTANT SAFETY INFORMATION
Individuals should **not** get the Pfizer-BioNTech COVID-19 Vaccine if they:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Individuals should tell the vaccination provider about all of their medical conditions, including if they:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects the immune system
- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

The vaccine may not protect everyone.

Side effects reported with the vaccine include:

- There is a remote chance that the vaccine could cause a severe allergic reaction▪ A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, vaccination providers may ask

individuals to stay at the place where they received the vaccine for monitoring after vaccination

- Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness
- If an individual experiences a severe allergic reaction, they should call 9-1-1 or go to the nearest hospital
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. Individuals should seek medical attention right away if they have any of the following symptoms after receiving the vaccine:
    - chest pain
    - shortness of breath
    - feelings of having a fast-beating, fluttering, or pounding heart
- Side effects that have been reported with the vaccine include:
    - severe allergic reactions; non-severe allergic reactions such as rash, itching, hives, or swelling of the face; myocarditis (inflammation of the heart muscle); pericarditis (inflammation of the lining outside the heart); injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); decreased appetite, diarrhea; vomiting; arm pain fainting in association with injection of the vaccine
- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away

Data on administration of this vaccine at the same time as other vaccines has not yet been submitted to FDA. Individuals considering receiving this vaccine with other vaccines, should discuss their options with their healthcare provider.

Patients should always ask their healthcare providers for medical advice about adverse events. Individuals are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit http://www.vaers.hhs.gov or call 1-800-822-7967. In addition, side effects can be reported to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

Please click here for full Prescribing Information (16+ years of age). Please click here for Fact Sheet for Vaccination Providers (12+ years of age). Please click here for the Recipients and Caregivers Fact Sheet.

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice
The information contained in this release is as of October 21, 2021. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162 mRNA vaccine program and COMIRNATY (COVID-19 Vaccine, mRNA) (BNT162b2) (including potential of booster doses, qualitative assessments of available data, potential benefits, expectations for clinical trials, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply) involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including the Phase 3 data), including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies or in larger, more diverse populations following commercialization; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for BNT162b2 in younger pediatric populations, applications for a potential booster dose and/or other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines that may arise from the BNT162 program, and if obtained, whether or when such emergency use authorization or licenses will expire or terminate; whether and when any applications that may be pending or filed for BNT162b2 (including the potential submissions for younger pediatric populations, a potential booster dose or any other requested amendments to the emergency use or conditional marketing authorizations) or other vaccines that may result from the BNT162 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's

benefits outweigh its known risks and determination of the vaccine's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers; the risk that demand for any products may be reduced or no longer exist; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's formulation, two-dose schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or new variant-specific vaccines; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

About BioNTech

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.de.

BioNTech Forward-looking Statements

This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer including the program to develop a COVID-19 vaccine and COMIRNATY (COVID-19 Vaccine, mRNA) (BNT162b2) (including a potential booster dose and emergency use authorization in the U.S. of a booster dose for individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age who have frequent institutional or occupational exposure to SARS-CoV-2; qualitative assessments of available data; potential benefits; expectations for clinical trials; the anticipated timing of regulatory submissions; regulatory approvals or authorizations and anticipated manufacturing, distribution and supply); our expectations regarding the potential characteristics of BNT162b2 in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on efficacy data of BNT162b2 in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and market demand, including our production estimates for 2021. Any forward-looking statements in this press release are based on BioNTech's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our productions capabilities; and other potential difficulties.

For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report as Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, which is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

CONTACTS

Pfizer:
Media Relations
+1 (212) 733-1226
PfizerMediaRelations@pfizer.com

Investor Relations
+1 (212) 733-4848
IR@Pfizer.com

BioNTech:
Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513
Media@biontech.de

Investor Relations
Sylke Maas, Ph.D.
+49 (0)6131 9084 1074
Investors@biontech.de

AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

Empowering rheumatology professionals to excel in their specialty

2200 Lake Boulevard NE, Atlanta, GA 30319
Phone: (404) 633-3777 • Fax (404) 633-1870 • www.rheumatology.org

COVID-19 Clinical Guidance for Adult Patients with Rheumatic Diseases

Developed by the ACR COVID-19 Clinical Guidance Task Force

This summary was initially approved by the ACR Board of Directors on April 11, 2020.

*A full paper (Version 1) was published on April 29, 2020, then copyedited/slightly revised into its final format, published in the August 2020 issue of Arthritis & Rheumatology.**

*New recommendations regarding reinitiating treatment following COVID-19 were added to this summary on July 13, 2020, and subsequently added to the full paper (Version 2), published in the September 2020 issue of Arthritis & Rheumatology.***

*Modifications specific to holding anti-malarial therapy after SARS-CoV-2 exposure or infection were made to this summary on November 16, 2020, and subsequently added to the full paper (Version 3), published in the February 2021 issue of Arthritis & Rheumatology.****

Purpose

The purpose of this document is to provide guidance to rheumatology providers on the management of adult rheumatic disease patients in the context of the COVID-19 pandemic. These statements are not intended to replace clinical judgment. Modifications made to treatment plans, particularly in complex rheumatic disease patients, are highly disease-, patient-, geography-, and time-specific and, therefore, must be individualized as part of a shared decision-making process. This guidance is provided as part of a 'living document,' recognizing rapidly evolving evidence and the anticipated need for frequent updates as such evidence becomes available.

Methods

The North American Task Force, including 10 rheumatologists and 4 infectious disease specialists, convened on March 26, 2020. Clinical questions were collated, and an evidence report was generated and disseminated to the panel. Questions and drafted statements were reviewed and assessed using a well-established method of consensus building (modified Delphi process). This included two rounds of asynchronous anonymous voting by email and two webinars including the entire panel. Panel members voted on agreement with draft statements using a numeric scoring system, and consensus was determined to be "low" (L), "moderate" (M) or "high" (H), based on the dispersion in voting results. To be approved as guidance, median votes were required to correlate to pre-defined levels of agreement (with median values interpreted as "agreement," "uncertainty" or "disagreement") with either moderate or high levels of consensus.

Recommendations

General statements for patients with rheumatic disease:

- The risk of poor outcomes from COVID-19 appears to be related primarily to general risk factors such as age and comorbidity (H).
- Patients should be counseled on general preventive measures, e.g., social distancing and hand hygiene (H).
- As part of a shared decision-making process between patients and rheumatology providers, select measures to reduce healthcare encounters and potential exposure to SARS-CoV-2 (beyond general preventive measures) may be reasonable, e.g., reduced frequency of lab monitoring, optimal use of telehealth, increased dosing intervals between intravenous medications) (M/H).
- If indicated, glucocorticoids should be used at the lowest dose possible to control rheumatic disease, regardless of exposure or infection status (M/H).

2200 Lake Boulevard NE, Atlanta, GA 30319
Phone: (404) 633-3777 • Fax (404) 633-1870 • www.rheumatology.org

- Glucocorticoids should not be abruptly stopped, regardless of exposure or infection status (H).
- If indicated, angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) should be continued in full doses or initiated (M/H).

Ongoing treatment of stable patients in the absence of infection or SARS-CoV-2 exposure:

- Hydroxychloroquine or chloroquine (HCQ/CQ), sulfasalazine (SSZ), methotrexate (MTX), leflunomide (LEF), immunosuppressants (e.g., tacrolimus, cyclosporine, mycophenolate mofetil, azathioprine), biologics, Janus kinase (JAK) inhibitors and non-steroidal anti-inflammatory drugs (NSAIDs) may be continued (this includes patients with giant cell arteritis with an indication, in whom IL-6 inhibitors should be continued, if available) (M/H).
- Denosumab may still be given, extending dosing intervals to no longer than every 8 months, if necessary to minimize healthcare encounters (M).
- For patients with a history of vital organ-threatening rheumatic disease, immunosuppressants should not be dose-reduced (M).

In patients with SLE:

- In newly diagnosed disease, HCQ/CQ should be started at full dose, when available (H).
- In pregnant women with SLE, HCQ/CQ should be continued at the same dose, when available (H).
- If indicated, belimumab may be initiated (M).

Treatment of newly diagnosed or active rheumatic diseases, in the absence of infection or SARS-CoV-2 exposure:

Active Inflammatory Arthritis:

- For patients well-controlled on HCQ/CQ, this disease-modifying anti-rheumatic drug (DMARD) should be continued, when available; when unable to access (including in patients with active or newly diagnosed disease), switching to a different conventional synthetic DMARD (either as monotherapy or as part of combination therapy) should be considered (M/H).
- For patients well-controlled on an IL-6 inhibitor, this DMARD should be continued, when available; when unable to access the agent, switching to a different biologic should be considered (M). The panel noted uncertainty regarding the use of JAK inhibitors in this situation.
- For patients with moderate to high disease activity despite optimal conventional synthetic DMARDs, biologics may be started (H). The panel noted uncertainty regarding the use of JAK inhibitors in this situation.
- For active or newly diagnosed inflammatory arthritis, conventional synthetic DMARDs may be started or switched (M).
- If indicated, low-dose glucocorticoids (≤10 mg prednisone equivalent) or NSAIDs may be started (M/H).

Other Rheumatic Diseases:

- In patients with systemic inflammatory or vital organ-threatening disease (e.g., lupus nephritis or vasculitis), high-dose glucocorticoids or immunosuppressants may be initiated (M).
- In the context of a drug shortage due to COVID-19, new HCQ/CQ prescriptions for non-FDA approved indications should be avoided (H).

Ongoing treatment of stable patients following SARS-CoV-2 exposure (without symptoms related to COVID-19):

- SSZ and NSAIDs may be continued (M/H).
- HCQ/CQ, immunosuppressants, non-IL-6 biologics, and JAK inhibitors should be stopped temporarily, pending 2 weeks of symptom-free observation (M). The panel noted uncertainty re: temporarily stopping MTX or LEF in this situation.
- In select circumstances, as part of a shared decision-making process, IL-6 inhibitors may be continued (M).

2200 Lake Boulevard NE, Atlanta, GA 30319
Phone: (404) 633-3777 • Fax (404) 633-1870 • www.rheumatology.org

Rheumatic disease treatment in the context of documented or presumptive COVID-19 infection:

- Regardless of COVID-19 severity, anti-malarial therapies (HCQ/CQ), SSZ, MTX, LEF, immunosuppressants, non-IL-6 biologics, and JAK inhibitors should be stopped or held (M/H).
- For patients with severe respiratory symptoms, NSAIDS should be stopped (M). The panel demonstrated low consensus with regards to stopping NSAIDs in the absence of severe symptoms.
- In select circumstances, as part of a shared decision-making process, IL-6 inhibitors may be continued (M).

Reinitiating Treatment Following COVID-19:

- For patients with uncomplicated COVID-19 infections (characterized by mild or no pneumonia and treated in the ambulatory setting or via self-quarantine), consideration may be given to re-starting rheumatic disease treatments (e.g., DMARDs, immunosuppressants, biologics and JAK inhibitors) within 7 to 14 days of symptom resolution. For patients who have a positive PCR test for SARS-CoV-2, but are (and remain) asymptomatic, consideration may be given to re-starting rheumatic disease treatments (e.g., DMARDs, immunosuppressants, biologics and JAK inhibitors) 10 to 17 days after the PCR test is reported as positive (H).
- Decisions regarding the timing of reinitiating rheumatic disease therapies in patients recovering from more severe COVID-19-related illness should be made on a case-by-case basis (H).

Updated November 16, 2020

How to cite this article:
Mikuls TR, Johnson SR, Fraenkel L, Arasaratnam RJ, Baden LR, Bermas BL, et al. American College of Rheumatology Guidance for the Management of Rheumatic Disease in Adult Patients During the COVID- 19 Pandemic: Version 1. Arthritis Rheumatol 2020;72:1241–51.

How to cite this article:
Mikuls TR, Johnson SR, Fraenkel L, Arasaratnam RJ, Baden LR, Bermas BL, et al. American College of Rheumatology Guidance for the Management of Rheumatic Disease in Adult Patients During the COVID-19 Pandemic: Version 2. Arthritis Rheumatol 2020; 72; e1-e12.

****How to cite this article:***
Mikuls TR, Johnson SR, Fraenkel L, Arasaratnam RJ, Baden LR, Bermas BL, et al. American College of Rheumatology Guidance for the Management of Rheumatic Disease in Adult Patients During the COVID-19 Pandemic: Version 3. Arthritis Rheumatol 2021; 73; e1-e12.
(https://onlinelibrary.wiley.com/doi/full/10.1002/art.41596)

AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

Empowering rheumatology professionals to excel in their specialty

2200 Lake Boulevard NE, Atlanta, GA 30319
Phone: (404) 633-3777 • Fax (404) 633-1870 • www.rheumatology.org

COVID-19 Vaccine Clinical Guidance Summary for Patients with Rheumatic and Musculoskeletal Diseases

Developed by the ACR COVID-19 Vaccine Clinical Guidance Task Force

*This summary was initially approved by the ACR Board of Directors on February 8, 2021 and updated on March 4, 2021. A full paper (Version 1), was published in Arthritis & Rheumatology on May 24, 2021.**

*New recommendations regarding mycophenolate, methotrexate, acetaminophen, and NSAID timing considerations+ were added to this summary on April 28, 2021 and were added to the full paper (Version 2), which was published in Arthritis & Rheumatology on June 15, 2021.***

*Updated recommendations regarding age restrictions, preferences between specific vaccines, and need for continued preventive measures were added to this summary on June 19, 2021 and were added to the full paper (Version 3), which was published in Arthritis & Rheumatology on August 4, 2021.****

Updated recommendations regarding preference for use of mRNA vaccines, use of a supplemental vaccine dose (i.e., 'booster'), and associated temporary interruption of immunomodulatory medications, and the FDA EUA for post-exposure prophylaxis with monoclonal antibody treatment for vaccinated AIIRD patients were added to this summary on August 19, 2021. These recommendations were added to the full paper (Version 4), which will be submitted to Arthritis & Rheumatology for publication.

Purpose

The purpose of this document is to provide guidance to rheumatology providers on the use of the COVID-19 vaccine and the associated management of rheumatic and musculoskeletal disease patients around the time of vaccination against SARS-CoV-2. These statements were based upon a dearth of high-quality data and are not intended to replace clinical judgment. Modifications made to treatment plans, particularly in complex rheumatic disease patients, are highly disease-, patient-, geography-, and time-specific and, therefore, must be individualized as part of a shared decision-making process. This guidance is provided as part of a 'living document,' recognizing rapidly evolving evidence and the anticipated need for frequent updates as such evidence becomes available.

Methods

The North American Task Force panel, consisting of 9 rheumatologists, 2 infectious disease specialists, and 2 public health experts with current or past employment at the Centers for Disease Control (CDC), convened multiple times in December 2020 and January 2021. The Task Force proposed a variety of clinical questions related to COVID-19 vaccination in patients with rheumatic and musculoskeletal diseases (RMD), divided itself into subgroups (i.e., teams), and assigned the clinical questions to the various teams by topic (e.g., vaccine effectiveness, safety). Each team was charged to generate an evidence review covering that topic; the evidence reviews were combined into an evidence summary document that was collated and disseminated to the entire Task Force. The Task Force reviewed the clinical questions and associated proposed vaccine guidance statements that were evaluated using a well-established method of consensus building (modified Delphi process). This process included two rounds of asynchronous anonymous rating by email and two live webinars including the entire Task Force. Panel members rated their agreement with draft statements using a numeric scoring system, and consensus was determined to be either "moderate" (M) or "high" (H), based on the dispersion in the rating results. To be approved as guidance, median ratings were required to correlate to pre-defined levels of agreement (with median values interpreted as "agreement," "uncertainty" or "disagreement") with either moderate or high levels of consensus based on the statements as they were originally voted upon, unless they were subsequently reconsidered. For this summary document, several rating statements that were initially separate were combined to facilitate clarity and conciseness.

Results and Conclusion

General considerations related to COVID-19 vaccination in rheumatic and musculoskeletal disease patients are shown in Table 1. Statements more specific to patient groups, as well as general disease- and timing-related considerations, are presented in Table 2. No evidence was found to support a concern regarding the use or timing of immunomodulatory therapies in relation to vaccine safety. Therefore, guidance regarding immunomodulatory medication and vaccination timing (Table 3) was given considering the intent to optimize vaccine response. An important set of guiding principles, foundational assumptions and limitations are mentioned in the Supplemental Table. The ACR is committed to updating this guidance as a 'living document' as new evidence emerges. Statements in **bold** are those that have been revised or added in the most current version of the document. These changes are also summarized in the Appendix Table.

Recommendations

Table 1: General Considerations Related to COVID-19 Vaccination in Rheumatic and Musculoskeletal Disease Patients

	Guidance Statement	Level of Task Force consensus
	The rheumatology healthcare provider is responsible for engaging the RMD patient in a discussion to assess COVID-19 vaccination status and engage in a shared decision-making process to discuss receiving the COVID-19 vaccine.	Strong-Moderate
	Acknowledging heterogeneity due to disease- and treatment-related factors, and after considering the influence of age and sex, AIIRD patients are at higher risk for hospitalized COVID-19 and worse outcomes compared to the general population.	Moderate
	Based on their risk for COVID-19, AIIRD patients should be prioritized for vaccination before the non-prioritized general population of similar age and sex.	Moderate
	Beyond known allergies to vaccine components, there are no known additional contraindications to COVID-19 vaccination for AIIRD patients.	Moderate
	The expected response to COVID-19 vaccination for many AIIRD patients on systemic immunomodulatory therapies is blunted in its magnitude and duration compared to the general population.	Moderate
	A theoretical risk exists for AIIRD flare or disease worsening following COVID-19 vaccination. However, the benefit of COVID-19 vaccination for RMD patients outweighs the potential risk for new onset autoimmunity.	Moderate

RMD = rheumatic and musculoskeletal disease; AIIRD=autoimmune and inflammatory rheumatic disease

Table 2: Recommendations for Primary and Supplemental Dosing of the COVID-19 Vaccine in RMD Patients

Guidance Statement	Level of Task Force consensus
RMD and AIIRD patients should receive COVID-19 vaccination, consistent with the age restriction of the EUA and/or FDA approval.*	Moderate
RMD patients without an AIIRD who are on immunomodulatory therapy should be vaccinated in a similar fashion as described in this guidance for AIIRD patients receiving those same treatments.	Moderate
For AIIRD patients not yet vaccinated, either of the mRNA vaccines is recommended over the single dose J&J vaccine.† There is no recommendation for one mRNA vaccine over another.	Moderate
For a multi-dose vaccine, AIIRD patients should receive the second dose of the same vaccine, even if there are non-serious adverse events associated with receipt of the first dose, consistent with timing described in CDC guidelines.	Strong
A single additional dose of Pfizer-BioNTech COVID-19 vaccine (age>= 12 years) or Moderna COVID-19 vaccine (age>=18 years) is recommended at least 28 days after the completion of the 2-dose mRNA vaccine series for AIIRD patients receiving any immunosuppressive or immunomodulatory therapy. These include the treatments listed in Table 3, including long term glucocorticoids, except for hydroxychloroquine. Attempts should be made to match the additional mRNA dose type to the type given in the mRNA primary series; however, if that is not feasible, a booster dose with the alternative mRNA vaccine is permitted.‡	Strong
Healthcare providers should not routinely order any lab testing (e.g., antibody tests for IgM and/or IgG to spike or nucleocapsid proteins) to assess immunity to COVID-19 post-vaccination, nor to assess the need for vaccination in a yet-unvaccinated person.§	Strong
Following COVID-19 vaccination, RMD patients should continue to follow all public health guidelines regarding physical distancing and other preventive measures.¶	Strong
Household members and other frequent, close contacts of AIIRD patients should undergo COVID-19 vaccination when available to them to facilitate a 'cocooning effect' that may help protect the AIIRD patient. No priority for early vaccination is recommended for household members.	Moderate
While vaccination would ideally occur in the setting of well-controlled AIIRD, except for those patients with life-threatening illness (e.g., in the ICU for any reason), COVID vaccination should occur as soon as possible for those for whom it is being recommended, irrespective of disease activity and severity.	Strong-Moderate

RMD = rheumatic and musculoskeletal disease; AIIRD=autoimmune and inflammatory rheumatic disease; EUA = emergency use authorization; FDA = Food and Drug Administration; mRNA = messenger RNA; CDC = Centers for Disease Control; ICU = Intensive Care Unit

*Age ≥12 as of June 7, 2021

† **This preference for the mRNA vaccines was partially driven by the fact that a supplemental dose is now authorized for the mRNA vaccines; this issue may be revisited if a supplemental dose strategy becomes authorized and recommended for patients who received the single dose vaccine.**

‡ **Given current uncertainties regarding the safety of providing supplemental dose(s) of an mRNA vaccine to patients who already have received the single-dose J&J vaccine, the panel did not achieve consensus regarding recommending supplemental dose(s) of the mRNA vaccine to patients who previously received the single-dose J&J vaccine. The terms "supplemental" and "boosting" are used interchangeably without regard to presumed mode of action, and whether intended to complete the primary vaccination series or to reverse waning of protection over time.**

§ **Given uncertainties in the interpretation of lab testing following vaccination as it would impact clinical decision-making, the panel reaffirmed this statement in Version 4 of this guidance document.**

¶ The Task Force discussed the possibility of recommending additional and more sustained public health measures in AIIRD patients. After deliberation, they did not elect to exceed current public health authority guidance given uncertainties about the clinical effectiveness of vaccination in such patients. The appropriateness for continued preventive measures (e.g., masking, physical distancing) should be discussed with patients as their rheumatology providers deem appropriate.

The panel also noted the August 2021 Emergency Use Authorization by the FDA for use of post-exposure prophylaxis using combination therapy with casirivimab and imdevimab (REGEN-COV) for prevention of COVID-19 in adults and pediatric individuals (age >=12) who are at high risk for progression to severe COVID-19. This EUA applies to individuals who are not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination. This at-risk group includes AIIRD patients and those receiving immunosuppressive or immunomodulatory therapy other than hydroxychloroquine.

Table 3: Guidance Related to the Use and Timing of Vaccination and Immunomodulatory Therapies in Relation to COVID-19 Vaccination in RMD Patients*

Medication	Timing Considerations for Immunomodulatory Therapy and Vaccination*	Level of Task Force Consensus
Hydroxychloroquine; apremilast; IVIG; glucocorticoids, prednisone-equivalent dose <20mg/day	No modifications to either immunomodulatory therapy or vaccination timing	Strong-Moderate
Sulfasalazine; Leflunomide; Azathioprine; Cyclophosphamide (oral); TNFi; IL-6R; IL-1; IL-17; IL-12/23; IL-23; Belimumab; Glucocorticoids, prednisone-equivalent dose ≥ 20mg/day†	No modifications to either immunomodulatory therapy or vaccination timing	Moderate
Mycophenolate; **oral calcineurin inhibitors**	Assuming that disease is stable, hold for 1 week following each vaccination	Moderate
Methotrexate	Hold MTX for 1 week after each of the 2mRNA vaccine doses, for those with well-controlled disease; no modifications to vaccination timing	Moderate
Methotrexate	Hold MTX for 2 weeks after single-dose COVID vaccination, for those with well-controlled disease	Moderate
JAKi	Hold JAKi for 1 week after each vaccine dose; no modification to vaccination timing	Moderate
Abatacept SQ	Hold SQ abatacept both one week prior to and one week after the first COVID-19 vaccine dose (only); no interruption around the second vaccine dose	Moderate
Abatacept IV	Time vaccine administration so that the first vaccination will occur four weeks after abatacept infusion (i.e., the entire dosing interval), and postpone the subsequent abatacept infusion by one week (i.e., a 5-week gap in total); no medication adjustment for the second vaccine dose	Moderate
Cyclophosphamide IV	Time CYC administration so that it will occur approximately 1 week after each vaccine dose, when feasible	Moderate
Rituximab	Assuming that patient's COVID-19 risk is low or is able to be mitigated by preventive health measures (e.g., self-isolation), schedule vaccination so that the vaccine series is initiated approximately 4 weeks prior to next scheduled rituximab cycle; after vaccination, delay RTX 2-4 weeks after final vaccine dose, if disease activity allows	Moderate
Acetaminophen, NSAIDs	Assuming that disease is stable, hold for 24 hours prior to vaccination (no restrictions on use post vaccination to treat symptoms)	Moderate
Supplemental Dosing (i.e., booster dose)		
All immunomodulatory or immunosuppressive therapies‡	**Except for glucocorticoids and anti-cytokine therapies (see footnote), hold all immunomodulatory or immunosuppressive medications for 1-2 weeks after booster vaccination, assuming disease activity allows.**	**Moderate**
Rituximab§	**Patients on rituximab or other anti-CD20 medications should discuss the optimal timing with their rheumatology provider before proceeding with booster vaccination.**	**Strong**

RMD = rheumatic and musculoskeletal disease; IVIG = intravenous immunoglobulin; TNFi = tumor necrosis factor inhibitor; IL = interleukin; JAKi = janus kinase inhibitor; CYC = cyclophosphamide; RTX = rituximab; IV = intravenous; SQ = subcutaneous; NSAID = non-steroidal anti-inflammatory drugs

**Guidance to 'hold' a therapy was made based on the assumption that the patient had well enough controlled disease to allow for a temporary interruption; if not, decision-making should be determined on a case-by-case basis, considering the circumstances involved*

† *Consensus was not reached for vaccination timing in patients receiving prednisone-equivalent doses ≥ 20mg/day; see full guidance document, when published, for additional details*

‡ ***The panel did not achieve consensus on whether to hold cytokine (e.g., IL-17, IL-12/23, IL-23, IL-1R, IL-6R) inhibitors at the time of booster vaccination.***

§***Some practitioners measure CD19 B cells as a tool with which to time the booster and subsequent rituximab dosing. For those who elect to dose without such information, or for whom such measurement is not available or feasible, provide the booster 2-4 weeks before next anticipated rituximab dose (e.g., at month 5.0 or 5.5 for patients on an every 6 month rituximab dosing schedule)***

IL-6R = sarilumab; tocilizumab; IL-1R = anakinra, canakinumab; IL-17 = ixekizumab, secukinumab; IL-12/23 = ustekinumab; IL-23 = guselkumab, rizankizumab; JAKi = baricitinib, tofacitinib, upadacitinib

Supplemental Table: Foundational Principles, Assumptions, and Considerations for the Guidance Statements

ACR guidance statements are not intended to supersede the judgement of rheumatology care providers nor override the values and perspectives of their patients. Guidance was based on weak and/or indirect evidence and required substantial extrapolation by an expert task force. All statements, therefore, should be considered conditional or provisional. The ACR is committed to updating this guidance document as new evidence emerges.
The rheumatology community lacks important knowledge on how to best maximize vaccine-related benefits. RMD patients exhibit high variability with respect to their underlying health condition, disease severity, treatments, degree of multimorbidity, and relationship with their specialist provider. These considerations must be considered when individualizing care.
Based on evidence published to date, the expected benefits of the COVID-19 vaccine outweigh the potential for vaccine harm in most RMD patients.
The future COVID landscape is uncertain with respect to vaccine effectiveness and safety, uptake, durability, mitigating societal behavior, and emerging viral strain variants. Clinicians nevertheless must act with their best judgement despite this highly uncertain and rapidly changing landscape.
The risk of deferring vaccination and thus failing to mitigate COVID-19 risk should be weighed against a possible blunted response to the vaccine if given under suboptimal circumstances. As a practical matter, this tension must be resolved in the context of imperfect prediction as to whether those circumstances may be transient, and a paucity of scientific evidence.
Both individual and societal considerations related to a limited vaccine supply should be considered in issuing vaccine guidance and making policy decisions. Given that context, simplicity should be the touchstone: to avoid confusion, improve implementation, and maintain scientific credibility.

RMD = rheumatic and musculoskeletal disease; mRNA = messenger RNA

[+] **Appendix Table 1: History of Major Changes to ACR COVID Vaccine Guidance Statements in the Summary Tables (i.e., this online document) and Locations in the Published Manuscript Tables and Prose Where Guidance Was Revised**		
Provided guidance to hold acetaminophen and NSAIDs for 24 hours prior to vaccination, assuming disease is stable	Table 5 (Summary Table 3)	Version 2
Modified guidance for mycophenolate to hold for 1 week after each vaccine dose	Table 5 (Summary Table 3)	Version 2
Modified guidance for methotrexate to hold for 1 week after each of the 2 mRNA vaccine doses, and for 2 weeks after single-dose COVID vaccine	Table 5 (Summary Table 3)	Version 2
Citations added describing the attenuation of SARS-CoV-2 vaccine response observed in patients receiving mycophenolate, methotrexate, janus kinase inhibitors, and other immunomodulatory therapies	Prose accompanying Table 5	Version 2
Age restriction lowered to age 12	Footnote to Table 3 (Summary Table 2)	Version 3
Preference for mRNA vs. non-mRNA vaccines	Footnote to Table 3 (Summary Table 2)	Version 3
Need for continued preventive measures	Footnote to Table 3 (Summary Table 2)	Version 3
Preference for two-dose mRNA vaccine over single-dose vaccine in AIIRD patients	**(Summary Table 2)**	**Version 4**
Recommendation for booster vaccination in AIIRD patients	**(Summary Table 2)**	**Version 4**
Recognition of the FDA Emergency Use Authorization for use of post-exposure prophylaxis with casirivimab and imdevimab (REGEN-COV) for prevention of COVID-19 in AIIRD patients	**(Summary Table 2)**	**Version 4**
Recommended temporary interruption of oral calcineurin inhibitors at time of vaccination	**(Summary Table 3)**	**Version 4**
Recommendations for temporary treatment interruption of various immunomodulatory therapies at the time of receipt of a vaccine booster dose.	**(Summary Table 3)**	**Version 4**

Recommendations updated April 28, 2021
Link to Version 1 manuscript added May 24, 2021
Link to Version 2 manuscript added June 15, 2021
Recommendations updated June 19, 2021
Link to Version 3 manuscript added August 4, 2021
Recommendations updated August 19, 2021
Link to version 4 manuscript pending

* **How to cite this article:**
Curtis JR, Johnson SR, Anthony DD, Arasaratnam RJ, Baden LR, Bass AR, et al. American College of Rheumatology Guidance for COVID-19 Vaccination in Patients with Rheumatic and Musculoskeletal Diseases – Version 1. Arthritis Rheumatol 2021. https://onlinelibrary.wiley.com/doi/10.1002/art.41734

******* **How to cite this article:**
Curtis JR, Johnson SR, Anthony DD, Arasaratnam RJ, Baden LR, Bass AR, et al. American College of Rheumatology Guidance for COVID-19 Vaccination in Patients with Rheumatic and Musculoskeletal Diseases – Version 2. Arthritis Rheumatol 2021. https://onlinelibrary.wiley.com/doi/full/10.1002/art.41877

******** **How to cite this article:**
Curtis JR, Johnson SR, Anthony DD, Arasaratnam RJ, Baden LR, Bass AR, et al. American College of Rheumatology Guidance for COVID-19 Vaccination in Patients with Rheumatic and Musculoskeletal Diseases – Version 3. Arthritis Rheumatol 2021. https://onlinelibrary.wiley.com/doi/10.1002/art.41928