Patients and Doctors Look to Mount Sinai for Guidance on COVID-19 and Biologic Drugs

By Mark G. Lebwohl, MD, Waldman Chair of Dermatology, The Kimberly and Eric J. Waldman Department of Dermatology, Icahn School of Medicine at Mount Sinai

Our Department has been at the forefront of biologic drug research and therapy for conditions like psoriasis, atopic dermatitis, alopecia areata, and some less common skin disorders. Drugs known as biologics target specific molecules called cytokines that are single factors in a patient’s immune system. For this reason, biologics are considered safer than older drugs like methotrexate, cyclosporin, and corticosteroids, which can cause overall immune suppression.

During the early days of the COVID-19 pandemic, patients were understandably worried that immune-modulating drugs like biologics might increase their susceptibility to COVID-19 or result in life-threatening infection. As a major center for biologic drug development and treatment, our practice was inundated with phone calls and email messages from concerned physicians and patients seeking guidance.

Telemedicine Brings the Dermatologist to You

Helping you to stay safe at home is a job we take seriously. The good news is that medical care provided via mobile devices and computers, known as telemedicine or telehealth, became widely available after Congress passed the CARES Act in March of this year. (CARES stands for Coronavirus Aid, Relief, and Economic Security.) The federal government temporarily relaxed some of the HIPAA privacy requirements along with other rules, so that health care providers may use popular platforms such as FaceTime, Skype, and Zoom, in addition to the standard HIPAA-compliant telehealth services.

Telemedicine visits can be provided in several ways. The most common of these is live, two-way video chat between a patient and a health care provider. Under certain circumstances, digital consultations using stored health data with prerecorded images and even telephone calls may qualify as reimbursable visits. Thanks to the CARES Act, a doctor may now provide telehealth services to both new and established patients, and patients may receive remote care from doctors who are licensed in other states. Although the regulations of individual states may vary from those of the federal government, many states, including New York and New Jersey, have relaxed in-state licensing requirements during the pandemic.

“The rationale for protecting health information still exists, even though the Department of Health and
Why Do We Need a Rapid Test for Lyme Disease?
By David S. Orentreich, MD, Assistant Clinical Professor of Dermatology, Icahn School of Medicine at Mount Sinai

During social distancing, one of the few favorable consequences has been greater enthusiasm for walking, hiking, and bicycling in uncrowded outdoor spaces. Let’s not forget, though, that Lyme disease is one of the risks of being in nature. Lyme disease is caused by bacteria known as *Borrelia burgdorferi*, which are transmitted to humans through the bite of an infected tick. About 30,000 cases of Lyme disease are reported to the Centers for Disease Control (CDC) each year, making it the most common insect-borne illness in the United States.

Diagnosing Lyme disease soon after onset is crucial because early treatment is usually curative. A delay, on the other hand, can lead to long-term effects on the joints, heart, and nervous system. A diagnosis can be made within a few days when a patient develops the characteristic rash called erythema migrans, commonly known as a bull’s-eye, but this sign is absent in about one-third of infected individuals.

A diagnosis of Lyme disease can also be confirmed with the traditional two-step blood test for antibodies that the immune system produces in response to infection. With current testing, these antibodies cannot be detected until about two to four weeks after infection. When there is a high degree of suspicion, a several-week course of an antibiotic such as amoxicillin or doxycycline is usually initiated while waiting for the results of the Lyme antibody test.

In recent days, there has been much talk about point-of-care testing. (Point-of-care refers to a diagnostic test that can be completed in a doctor’s office or hospital while the patient waits for results.) Rapid testing is particularly important for infectious diseases, because a few days saved can make a big difference in medical decision-making. There is currently great interest in a rapid point-of-care assay for Lyme disease that was reported in the *Journal of Clinical Microbiology* in 2019.

Currently in development, the Lyme disease point-of-care assay uses a method called microfluidics that has been reported to be faster and more accurate at detecting early biomarkers of Lyme disease than the two-step test currently in use. Not only would the new test be more sensitive during the early stages of disease, but as a rapid point-of-care test, it could save five to ten days of waiting for results.

The National Institutes of Health (NIH) advise that although the study’s authors say the new test shows great potential, it requires refinement, testing, and FDA approval. It is still too early to predict exactly when the test will become available.

For more information about Lyme Disease, visit www.cdc.gov/lyme/
Guidance on COVID-19 and Biologic Drugs continued from page 1

It is important to know that COVID-19 is a novel coronavirus, meaning it is a new virus—we had no data before this outbreak. What we did have were many placebo-controlled clinical trials of every biologic drug’s impact on all infections, and in particular, respiratory tract and viral infections like the flu and common colds.

During clinical trials of biologic drugs for psoriasis, the rate of respiratory tract infection for the majority of biologics was similar to the placebo rate. However, infection rates did turn out to be significantly higher for the Tumor Necrosis Factor (TNF) blockers that include Remicade®, Humira®, and Cimzia®. These and another TNF blocker, Enbrel®, carry FDA boxed warnings cautioning patients about infections, including viral infections.

The newer biologic drugs that block cytokines called interleukins (IL) had very low rates of respiratory infection, similar to placebo. This category includes the IL-12 and IL-25 blocker Stelara®; IL-17 blockers like Cosentyx®, Taltz®, and Siliq®; and IL-25 blockers such as Tremfya®, Ilumya®, and Skyrizi®. It is worth noting that the IL-17 blocking drugs are known to predispose to yeast infections but not to viral infections.

Based on all the data, we decided to offer patients currently treated with TNF blockers the option to switch to the newer IL-17 and IL-25 blocking drugs. Our experience predicts that these would be safer during a viral outbreak. The IL-17 and IL-25 blockers also tend to be the most effective.

If a patient on a biologic drug tests positive for COVID-19 infection, we withhold the drug until the patient has fully recovered. But for uninfected patients whose skin diseases are well controlled on biologics, discontinuing biologics drugs would not be my recommendation. A stop-and-start approach has been shown to yield a lower improvement rate after restarting the drug than a patient could expect from continuous treatment.

For patients on the biologic drugs Dupixent® for atopic dermatitis and Xolair® for hives, discontinuing the drugs might be detrimental when it comes to respiratory infections. These patients are prone to asthma, which is kept under control with the drugs. Withholding Dupixent or Xolair might worsen asthma and increase the patient’s risk of serious pneumonia from COVID-19.

I was invited to present our guidelines to an international audience of dermatologists at a webinar in March of this year. Subsequently, a number of medical organizations and patient-advocacy groups have issued very similar recommendations. We are constantly learning about the novel coronavirus and will continue to analyze the data in the months to come. In the meantime, a compassionate approach to the care of each individual allows us to find the balance between treatment success for skin disorders and risk mitigation during a viral outbreak.

Telemedicine Brings the Dermatologist to You continued from page 1

Human Services stated that it will not enforce HIPAA privacy rules during the pandemic,” says George Han, MD, Director of Teledermatology for the Mount Sinai Health System. “With numerous publicly available videoconferencing applications, information security is a concern.” Dr. Han pointed to popular platforms in which hackers might be able to observe communications containing sensitive information. “While the likelihood of this affecting an individual patient encounter is low, I favor HIPAA-compliant telehealth services for the best privacy protection. These will also help providers to continue offering remote care when the pandemic is over,” says Dr. Han.

Many physicians are joining the telehealth movement. It makes sense to find out about the remote services your doctor will provide when you need to stay at home. We recommend asking your insurer if you are responsible for copays or other fees.

Mount Sinai Doctors Faculty Practice is now offering teledermatology appointments to new and established patients of all ages. To book a visit, call 212-241-9728 or email DermAppointmentRequest@mountsinai.org.

For more information, see the Medicare COVID-19 telehealth fact sheet at https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf
## Major Multiyear Gifts

- Mr. John Chr. M.A.M. Deuss
- Dow Family Charitable Fund
- The Orentreich Family Foundation
- Kimberly and Eric J. Waldman

### $150,000+

- Mr. and Mrs. Mark F. Dalton
- Gary Goldenberg, MD, and Kristina Goldenberg, MD
- Mrs. Susan Kornstein
- Mr. Juan S. Lui
- Mr. and Mrs. John H. Szalkay

### $100,000 to $149,999

- Mr. and Mrs. William Ryan
- Leslie C. Feldman, Esq.
- Ms. Kate Hoban
- Mr. and Mrs. Morris Mark
- Dr. Rita C. O’Connor and Mr. Theodore H. Schell

### $20,000 to $99,999

- Susan V. Bershad Charitable Fund
- Leon Kircik, MD
- Mrs. Janet C. Ross
- Mr. and Mrs. Jeffrey G. Schlein
- Mr. and Mrs. Martin V. Schwartz
- Nina W. Werblow Charitable Trust

### $10,000 to $19,999

- Mr. and Mrs. Lawrence D. Ackman
- Ms. Susan J. Berne and Mr. Leonard Aconsky
- Lance Barazani, MD
- Eric Z. Berkowitz, MD, and Claire D. Berkowitz, MD
- Whitney Bowe, MD
- Gary J. Brauner, MD
- Mr. and Mrs. Clyde R. Brownstone
- Mr. Peter M. Buchman
- Karen E. Burke, MD, PhD
- Mr. Stanley Chase
- Stephen Comite, MD
- Ms. Mary Steenburgen and Mr. Edward B. Danson
- Michael E. Eidelman, MD
- Ms. Bobbie Falk
- Mr. Elias Feuer
- Mrs. Rita R. Fleischmajer
- Mr. and Mrs. Darren Fogel
- Joshua L. Fox, MD
- Paul J. Frank, MD
- Suzanne J. Friedler, MD

### $5,000 to $9,999

- Robert L. Warner, MD
- Mr. and Mrs. Stanford S. Warshawsky
- Ms. Anne Marie W. Wermers
- Patricia S. Wexler, MD
- Ms. Evelyn Z. Zafra

### $2,500 to $4,999

- Ms. Margaret A. Bancroft
- Mr. and Mrs. Mark S. Marinovich
- Ellen S. Marmur, MD, and Jonathan D. Marmur, MD
- Shira R. Maryles, MD
- Mr. and Mrs. Mervin A. Matlin
- Sheryl R. Miller, MD
- Robert Nossa, MD
- Frederick A. Pereira, MD
- The Reinsberg Family Foundation
- Mr. and Mrs. Bernard Rome
- Yulianna Russak, MD
- Dr. and Mrs. Allen N. Sapadin
- Lisa M. Silbret, MD, and Alan L. Schechter, MD, PhD
- Michael Shapiro, MD
- Ron M. Shelton, MD
- James M. Spencer, MD
- Mr. and Mrs. Matthew M. Steinfeld
- John Troccoli, MD
- Dr. and Mrs. Walter P. Unger

(continued on page 5)
Thank You to Our Supporters in 2019 continued from page 4

$500 to $999 (continued)
Abraham R. Freilich, MD
Suzanne Friedler, MD
Francesca J. Fusco, MD
Ms. Virginia J. Getz
Dr. Barry Goldman
Mr. and Mrs. Eugene J. Glaser
Elizabeth I. Goldberg, MD
Valerie Goldburt, MD, PhD
Mr. and Mrs. Alan Q. Golub
Michele S. Green, MD
Mr. Harley J. Greenfield
Carin H. Gribetz, MD, and
Mr. Eric Gribetz
Ahmed S. Hadi, MD
Karen Hammerman, MD
Mr. and Mrs. Jack B. Hartog
Virgil Hatcher, MD
Marie V. Hayes, MD
Bruce Heller, MD
Dr. Cindy Hoffman and
Dr. Mitchell Fischer
Kenneth L. Howe, MD
Stephanie Hu, MD
Peter Ilowite, DO
Samer Jaber, MD
Mr. and Mrs. William Silver
Elizabeth Smith, MD
Dana K. Stern, MD
Michael Shapiro, MD
Daniel W. Sherer, MD
Sherry Shieh, MD
Mr. and Mrs. William Silver
Elizabeth Smith, MD
Dana K. Stern, MD
Michael Shapiro, MD
Daniel W. Sherer, MD
Sherry Shieh, MD
$100 to $499
Hyun Soo Lee, MD
Jody A. Levine, MD, and
Elie Levine, MD
Robert Levine, MD
Dominick Joseph Ligresti, MD
Lian A. Mack, MD
Adarsh V. Mudgil, MD
Mr. and Mrs. T. Newberry
Charlotte Noorollah, DO
Payal S. Patel, MD
Carolyn Penrose, MD
Morgan E. Rabach, MD
Helen Radoszyczki, MD
Jeffrey Roth, MD, PhD
Neal B. Schultz, MD
Michael Shapiro, MD
Daniel W. Sherer, MD
Sherry Shieh, MD
Mr. and Mrs. William Silver
Elizabeth Smith, MD
Dana K. Stern, MD
Michael Shapiro, MD
Jack P. Tom, MD
Susan L. Ungar, MD
Robin Unger, MD
Ms. Zenia R. Wand
Debra J. Wattenberg, MD
Mr. and Mrs. Eric C. Woglom

Mr. Daniel H. Burdick, II
Ms. Dierdre A. Burgman
Ms. Kathleen Cafaro
Mr. and Mrs. Dan Carlinsky
Mr. James H. Cole
Mr. and Mrs. Joseph Correia
Mr. and Mrs. Arthur V. Doscher, Jr.
Amanda Doyle, MD
Mr. Theodore Drucker
Meghan A. Feely, MD
Mr. John H. Fitzsimons
Zoila Flashner, MD
Mr. and Mrs. Stephen G. Flax
Rabbi and Mrs. David Gaffney
Mr. Howard L. Gerber
Ms. Roberta J. Giani
Robyn Gmyrek, MD
Mr. and Mrs. Peter Goldblatt
Jeannette Graf, MD, and
Jeffrey H. Graf, MD
Jodi Grossfeld, MD
Mr. Arthur J. Groszhandler
Tatyana Groysman, MD
Alison B. Gruen, MD
Robin Unger, MD
Mr. and Mrs. Lawrence E. Kahn
Mr. and Mrs. David R. Kamenstein
Ms. Frances N. Kennedy
Mr. and Mrs. Alan Kerah
Mr. Frederick Kriegl
Joan Pirie Leclerc Trust
Mr. and Mrs. Edward Lewit
Mr. and Mrs. Lorraine Lieberman
Ms. Judith Love
Dr. and Mrs. Fred D. Lublin
Mr. and Mrs. J. Kevin Madden
Mr. and Mrs. Solomon Magid
Ms. Carolann F. Marshall
Ms. Judith Moses
Adam Nabatian, MD
Ms. Shirley A. Onacilla
Mr. and Mrs. J. Oppenheim
Mr. and Mrs. Howard Permut
Mr. and Mrs. Kenneth A. Plevan
Tara Rao, MD
Dr. Marion T. Rodriguez
Michael T. Romano, MD, and
Ms. Lauren E. Fonseca
Dr. Barry N. Rosen
Mr. Stanley Salt
Mrs. Rita Schreiber
Mr. Ronald Semaria
Ms. Ayman E. Svatnsnaider
Mr. and Mrs. Arnold W. Syrop
Mrs. Naomi Wahrman
Mr. and Mrs. Joseph W. Wallen
Ms. Beth A. Willensky and
Mr. Herbert Feuerstein
Mr. Yehuda Leon Yaloz
Jane Yoo, MD

Under $100
Dr. Faina Baranov and
Mr. Vladimir Baranov
Ms. Yitty Blumenfeld
Mr. David Cunningham
Mr. William Gelfman
Mr. Joseph M. Gell, Jr
Mrs. Eva Hermann
Ms. Catherine King
Mr. and Mrs. Thomas J. Mulligan
Ms. Sandra Oleck
Ms. Eileen M. Ryan
Ms. Gertrude Sapossnek
Mr. and Mrs. Louis Scaturro
Mr. and Mrs. Richard J. Scollo
Ms. Marilyn Segal
Ms. Paula A. Wagner
Ms. Elizabeth Yarbrough
Ms. Freddy Zaiter

PLEASE CONSIDER A TAX-DEDUCTIBLE CONTRIBUTION TO DERMATOLOGY RESEARCH AND EDUCATION

Please fill out both sides, detach this form and mail to:
The Kimberly and Eric J. Waldman Department of Dermatology
One Gustave L. Levy Place, Box 1047
New York, NY 10029-6574

Please contact us by telephone at 212-659-8500 or email your name and address to PhilanthropyOptOut@mountsinai.org if you wish to have your name removed from our distribution list of fundraising materials.
When Words Are Not Enough

The spring of 2020 has been a season like no other. An invisible virus is taking its toll on each and every patient, friend, and neighbor of Mount Sinai. The Kimberly and Eric J. Waldman Department of Dermatology wants to express our sadness and concern to those of you who have lost loved ones or endured illness.

We salute our heroes—health care workers on the front lines (including many of our own), first responders, and essential workers—for stepping up in ways not imagined for over a century. We want to say THANK YOU to every family in the tri-state area and beyond for your personal sacrifices and for your outpouring of appreciation for our doctors, nurses, and support staff. You lift their spirits and inspire them to carry on.

Most of Mount Sinai’s Dermatology Residents and many members of our faculty and staff were deployed to the front lines to care for COVID-19 patients.