ACR Aims Guidance on Biologics' Use at Payors

BY SALLY KOCH KUBETIN

Insurance payers now have detailed guidance on the appropriate use and coverage of biologic agents in the management of rheumatoid arthritis, thanks to a document prepared by the American College of Rheumatology.

"Insurance companies would like to put the various biologics on the market in rank order," according to Dr. Karen S. Kolba, chair of the ACR's Committee on Rheumatologic Care.

Although the Food and Drug Administration and the agents' labels do indeed spell out which patients are candidates for which agents, insurers would like to make that determination more formal and binding, such that a patient must fail to respond to drug A and drug B before receiving drug C.

In the case of rituximab (Rituxan), the FDA recommends that a patient with RA must have failed to respond to a tumor necrosis factor–blocking agent before being considered as a candidate for this B cell–depleting therapy, a position that most rheumatologists would find reasonable.

Problems arise when an insurer decrees that patients may receive rituximab only when they have failed to respond to all other biologic therapies.

"Some [agents] are given subcutaneously and some are self-administered. The self-administered agents may be less expensive, depending on the dose needed. But rituximab is a reasonable choice for some patients, even though it is infused," said Dr. Kolba, who is in private practice in Santa Maria, Calif.

By developing this guidance document, the ACR continues to show insurers that the college remains a fair and reasonable source of information on the drugs 'that are best for our patients.'

The ACR's Model Biologics Policy 2010, which is available to members through the ACR Web site, lists the HCPCS (Healthcare Common Procedure Coding System) code sets for each biologic.

Also listed are the CPT codes for the drugs' routes of administration and the ICD-9 diagnosis codes for every clinical conditions for which a biologic agent is an appropriate, indicated treatment.

The policy also details the medically necessary, FDA-approved indications for each biologic.

For example, adalimumab (Humira) has the following indications: rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, and plaque psoriasis.

The ACR's policy notes that special considerations with the use of adalimumab include the need to test for active or latent tuberculosis, to monitor hepatitis B virus carriers during treatment for reactivation, and to monitor those patients who are taking concomitant anti-TNF-alpha therapy such as anakinra (Kineret) or abatacept (Orencia), which would increase the risk of infection.

The policy lists the possible off-label uses for the agents as well as information on the route of administration and dosing.

Regarding etanercept, the policy notes that the agent may be used in combination with methotrexate or as monotherapy in RA. Golimumab (Simponi) must be used in combination with methotrexate.

The use of anakinra is appropriate in patients with severely active RA who have failed to respond to at least one disease-modifying antirheumatic drug.

Dr. Kolba added that insurance companies are already in the habit of seeking the ACR's guidance on issues relating to the appropriate use of biologics, so there is a precedent of their following these recommendations.

With this guidance document, the ACR continues to show insurers that the college remains a fair and reasonable source of information on the medications "that are best for our patients," Dr. Kolba told RHEUMATOLOGY NEWS. "Expensive drugs may prove to be the most cost effective because they control disease activity and prevent joint destruction." ■

The policy is available online at www.rheumatology.org/practice/office/insurance/Model_Biologics_Policy.pdf#search="model biologics policy".

Court Ruling Puts Embryonic Stem Cell Research in Limbo

BY MARY ELLEN SCHNEIDER

With the federal government filing an injunction, a fight is looming over the future of federal funding for research using human embryonic stem cells. The fracas started with an earlier ruling by a federal judge that temporarily blocked such research funding, leaving researchers who study human embryonic stem cells calling themselves surprised, disappointed, and even angry.

The Obama administration responded by filing a stay and notice of appeal on August 31.

The contested federal ruling bars the use of federal funds for any research involving human embryonic stem cells. As a result of the temporary injunction, the National Institutes of Health has stopped accepting submissions of information on human embryonic stem cell lines for NIH review and has also suspended all review of embryonic stem cell lines.

President Obama expanded opportunities to receive federal funding for embryonic stem cell research when he issued an executive order in 2009 that eliminated many of the restrictions placed on funding during the George W. Bush administration. The NIH followed with guidelines that allowed research to be conducted on embryonic stem cells derived from embryos created through in vitro fertilization and donated for research.

With the recent court decision, some researchers worry that the development of therapies that use embryonic stem cells will be set back and that the loss of federal funding will have a chilling effect on newly minted researchers who are considering whether to enter the field.

By siding with the plaintiff, this judge opens the door for every scientist who ever has a grant request rejected to sue the federal government.

The halt on funding for research using embryonic stem cells has implications on all types of stem cell research, said Alan Trounson, Ph.D., president of the California Institute for Regenerative Medicine, which issues grants to researchers in California who use state funds. "The decision is a deplorable brake on all stem cell research," he said in a statement. "Many discoveries with other cell types, notably the so-called reprogrammed [induced pluripotent stem] cells, would not happen without ongoing research in human embryonic stem cells."

Dr. Trounson said the California institute's funding plans would not be affected by the federal court decision. Institutions that have obtained private funding for their stem cell work will also be able to continue that work. However, even those with deep pockets are concerned that private funding alone is not enough. "It's a blow to us," said B.D. Colen, a spokesman for the Harvard Stem Cell Institute.

The institute , a collaborative of stem cell researchers from around Massachusetts, has raised about $120 million in private funds since its founding 2004, but those sources are not unlimited, Mr. Colen said. The loss of federal funding that was expected to go to the institute's researchers will be disruptive, he said, and the impact will be worse for those researchers who do not have private funding sources to fall back on.

Another source of concern for researchers has to do with the legal issues involved in the case. An earlier lawsuit challenging the Obama stem cell guidelines had been dismissed after the court ruled that the plaintiffs had no standing to challenge it. However, the recent injunction came about after the court decided that two researchers who work with adult stem cells could challenge the guidelines because funding of embryonic stem cell research was harming their chances for receiving federal funds for adult stem cells.

"This judge opens the door for every scientist who ever has a grant request rejected on the merits to sue the federal government," the American Society for Reproductive Medicine said in a statement condemning the court decision.

In granting the temporary injunction, Judge Royce C. Lamberth, the chief judge in the U.S. District Court for the District of Columbia, said the NIH guidelines violated the intent of Congress to bar the use of federal funds for research in which human embryos are destroyed. He said the rules violated the Dickey-Wicker amendment, a rider generally attached to health spending bills each year. It prohibits the use of federal funds for the creation of a human embryo or embryos for research purposes or research in which a human embryo or embryos are destroyed or discarded. However, the Obama administration has argued that the amendment doesn't apply because federal funds are used for research on the embryonic stem cell lines, not in the destruction of the embryos.

Judge Lamberth said: "[Embryonic stem cell] research is clearly research in which an embryo is destroyed. Despite defendants' attempt to separate the derivation of [embryonic stem cells] from research on the [embryonic stem cells], the two cannot be separated." ■