AMERICAN COLLEGE OF RHEUMATOLOGY
POSITION STATEMENT

SUBJECT:	The Complexity of Biologics and their Coverage and Payment
PRESENTED BY:	Committee on Rheumatologic Care
FOR DISTRIBUTION TO:	Members of the American College of Rheumatology Medical Societies Members of Congress Centers for Medicare and Medicaid Services Managed Care Organizations/Third-Party Carriers Insurance Companies and Commissioners Other interested parties

ACR POSITIONS

1. The use of biologics should be supervised and carried out by specially trained physicians and advanced practitioners. These experts have the required knowledge, training and experience to properly handle and administer biologic agents and monitor for adverse reactions.

2. All providers and payers should follow consistent policies for documentation of medical necessity, complex administration protocols, and proper coding and reimbursement for the infusion and injection of biologics.

3. All biologic agents should be covered at an appropriate level by all health plans and considered highly complex for purposes of administration, monitoring, coding and reimbursement.

4. Biologics with separate formulations, such as those administered by subcutaneous versus intravenous routes, are distinct with sufficiently unique indications, risks and target patient populations to warrant unique CPT codes.

5. Polices on biologic administration location should promote the highest standards of safety and allow patients to obtain their treatments in medical facilities with specially trained practitioners overseeing their infusion.

BACKGROUND

The American College of Rheumatology strongly supports the use of complex biologic agents as necessary treatments for rheumatic diseases and many other disease states. The molecular structure, size, manufacturing, storage, and administration of these drugs, as well as their potential to cause serious adverse events, all contribute to their complexity. This complexity far exceeds that of traditional pharmaceuticals. In addition, the tremendous heterogeneity of patients with autoimmune disease and the diversity of conditions treated with biologics require that highly trained, specialized clinicians oversee their safe and effective administration. The ACR promotes the highest quality guidelines[1] and best practices for treatment with biologics.

BIOLOGICS ARE MEDICALLY NECESSARY

Arthritis is the leading cause of disability in the US and modern approaches to treatment have revolutionized outcomes for patients with these diseases. Early aggressive therapy with a range of drugs, including biologics, has been shown to reduce joint damage, deformities and improve function which can reduce work absenteeism, disability, death, costly procedures/surgeries and hospitalizations.[2] In spite of their up-front costs, the addition of biologics to other treatment modalities has been shown to be cost-effective when used in appropriate patient populations.[3,4]

The ACR has issued a separate statement on the indications and caveats for medical necessity of biologics.[5] This document addresses the standards for proper documentation of medical necessity of biologics. It also explains the common clinical circumstances requiring the use of intravenous biologics as opposed to self-administered biologics. In addition, the ACR has provided position papers that detail the FDA indications, appropriate use, safety, and off label use for biologics. Finally, policies for switching between biologics are addressed in a position paper entitled "Patient Access to Biologics."[6]

BIOLOGICS ARE COMPLEX MOLECULES

Biologics are far more complicated at the molecular level than traditional chemically synthesized pharmaceuticals. They are much larger molecules than other classes of pharmaceuticals with an average molecular mass 1000 times greater than aspirin. Their size and biologic properties preclude oral administration, a fact which complicates storage and delivery to patients.

In contrast to chemically synthesized pharmaceuticals, most biologics have multiple functional domains per molecule. The most common type of recombinant biologic used by patients with rheumatologic conditions is monoclonal antibodies. These have two antigen-binding (attach to the target of interest) domains per molecule. In addition, each antibody molecule contains an Fc domain that can bind a range of proteins *in vivo* with dramatic effects on the drug's mechanism of action and therapeutic half-life.

Further complexity of biologics derives from their manufacturing which occurs in living cells. Production of these agents requires highly technical processes and reagents that must be exquisitely controlled and monitored. Generation of a recombinant biologic starts with a rationally designed DNA sequence (a gene) that must be expressed in a host system. Host systems used to produce biologics include bacteria, yeast, insect cells, transgenic animals, and human or other mammalian cell lines. Targeted DNA sequences are transcribed and then translated by the host cell into peptides that fold and combine into proteins with highly complex tertiary and quaternary structures. This process is accompanied by post-translational modifications of the proteins (including, but not limited to, glycosylation, oxidation and phosphorylation) that affect their efficacy, stability and immunogenicity.

The host cell and the conditions under which the proteins are generated and purified (especially temperature, pH, cell density, oxygenation and osmolality) can have dramatic effects on post-translational modifications and the purity of the final product. This impacts the efficacy, immunogenicity and safety of the drug.[7] Finally, precipitation and aggregation of protein complexes that can take place during the manufacturing and storage of these agents further impacts their stability, efficacy and tolerability. These complexities necessitate the tremendous

care (especially with respect to temperature, mechanical agitation and proper reconstitution) that must be taken to ensure proper delivery and administration of these drugs to patients.

Not surprisingly, given the complexity associated with the design, manufacturing and storage of biologics, differences over time in the structure, efficacy and safety of biologics have been observed. These changes are expected as part of batch-to-batch variability during the production of a given drug and have been reported with etanercept and rituximab.[8] There are also unavoidable complications in the development of new agents, including biosimilars.[9] These changes often result in the failure of a drug to work as intended.

Thus, complexities in the structure, generation, storage and delivery of biologics impart significant differences over time not only to various agents within a therapeutic class (such as TNF inhibitors) but also to the very same product generated by the same manufacturer.

PATIENT FACTORS ADD COMPLEXITY TO BIOLOGICS

The patient's experience with biologics illustrates the importance of these complexities. For example, if the efficacy of a TNF inhibitor were determined solely by its ability to neutralize TNF (which is similar among all agents in this class), then individual patients would experience the same therapeutic benefit regardless of the TNF inhibitor used. This is clearly not the case as patients and their physicians alike routinely observe marked variability in the efficacy and tolerability of different biologics, even those in the same class, and even in an individual patient over time. The structure of the drug, impacted by its design, manufacture and storage, as well as its stabilizers, diluent and route of delivery, are reasonable (and not mutually exclusive) explanations for the variable response and variable tolerability observed.

BIOLOGICS AND SERIOUS ADVERSE EVENTS

All classes of biologics used in autoimmune diseases may cause serious adverse events. Adverse reactions occur 1) with all classes of immune-modulatory biologics; 2) in nearly half of patients receiving these medicines; 3) following subcutaneous and intravenous administration; and 4) in an immediate or delayed fashion.

Adverse events associated with biologics include, but are not limited to, injection site reactions, infusion reactions, exacerbation of heart failure, cytopenias, infections (including lethal tuberculosis and fungal infections), increased risk of skin cancer, demyelinating diseases (such as multiple sclerosis), and the development of autoantibodies and clinical manifestations of drug-induced systemic lupus erythematosus. Proper screening for occult infections and other co-morbidities is therefore required before biologics are prescribed. In addition, ongoing expert monitoring for any new or developing co-morbidities is also required to minimize the potential for harm.

Adverse drug reactions associated with biologics are common. For instance, 42% of patients treated with etanercept have injection site reactions.[10] Infusion reactions, which range in severity from a mild rash to life-threatening anaphylaxis, can happen acutely or several days after the infusion. For example, the administration of infliximab is associated with acute infusion reactions in 10% of patients. Reactions can occur after or during infusion therapy and 1% of infusions cause reactions that are classified as severe.[11] Serious infections occur at a similar rate across all the immune modulatory biologics and affect 2-5% of patients per year of exposure.

BIOLOGICS, EVEN WITHIN A CLASS, ARE NOT INTERCHANGEABLE

Biologics, even within a class, are not equivalent in their indications, efficacy, safety, or tolerability. Differences between biologics determine both the choice of medication for a patient as well as the method of delivery. Medical factors that influence the choice of drug and route of administration include patient age, duration and extent of disease, prior adverse events, physical limitations, extra-articular manifestations of disease, comorbid conditions, and overlap with other rheumatologic and non-rheumatologic conditions. For example, wide differences in response to anti-TNF therapies are seen in inflammatory bowel diseases, inflammatory arthritis, and psoriasis; all specialties observe variable responses with anti-TNF therapies.

Even drugs marketed under the same name, but administered by different routes, are not interchangeable. In one study, 27 per cent of rheumatoid arthritis patients who were switched from IV to SQ formulations of abatacept suffered relapses of their disease which responded to re-initiation of therapy with the original IV formulation of the drug.[12]

COVERAGE AND PAYMENT POLICIES FOR BIOLOGICS

In addition to the scientific and clinical expertise required to manage these drugs, biologics require specialized approval processes and proper coding and impose substantial burdens on practices above and beyond that associated with other therapies. Approval processes require specialized forms and ongoing communication with specialty pharmacies, pharmacy benefit managers and insurers. Often, letters of medical necessity and additional documentation are necessary to obtain approval for biologics. Once they are approved, additional counseling, education, and coordination of care are required at the point of care for administration. In preparation of administration, biologics require additional time beyond other therapies for reconstitution and administration of the drug. When these medications are administered in an office setting, the service is reported using guidelines developed by the American Medical Association's Current Procedural Terminology Editorial Panel. These guidelines reflect the increased training and expense required to administer biologics compared to simple, non-complex therapy such as hydration or antibiotics.

While complex biologic agents are not necessarily combustible or caustic on contact with the skin like older agents, they require specialized handling above and beyond that required for the preparation of non-biologics. For example, biologics in some settings require a hood; others must be protected from sunlight, agitation and variations in temperature; some must be prepared with silicone-free materials. The comprehensive work required to approve, administer and monitor complex biologics exceeds that of traditional injection or infusion medications.

Most notably, all specialty societies find that biologics meet the definitions for chemotherapy services according to CPT and CMS manuals.[13,14] Whether a drug is administered by dermatology, gastroenterology, oncology, or rheumatology, reimbursement for intravenous biologics should be consistent across all specialties. For example, rituximab is approved for both oncology and rheumatology diagnoses and rheumatologists and oncologists follow similar infusion protocols to administer this complex chemotherapy agent.

Similar to chemotherapy agents administered in oncology, biologics carry high potential toxicity, and supervising practitioners must assure the purity of the biologic materials they administer and

be sure it has not been compromised. The use of materials for infusion or injection supplied directly to patients or providers from specialty pharmacies, so called "brown bagging", carries a higher risk to the patient. Examples of problems that pose particular threats to a patient when the chain of custody is broken or unknown include inadequate temperature control, leakage, and expiration. In addition, dispensing drugs directly to patients places burdens on the patients that they are not trained or qualified to handle.

The involvement of additional parties beyond the patients further increases the risk of mishandling. There have been instances of fraudulent dilution of materials for profit by intermediaries. Also, expensive biologics are necessarily wasted when the decision is made to stop therapy at the point of care but after the drug has been dispensed to the patient. Thus, in accordance with their responsibility to provide care that is above all safe, practitioners require a chain of custody which can be audited. The ACR therefore promotes direct delivery of biologics from the pharmacy to the facility administering the biologic.

As the ACR has previously outlined: Because chemotherapy services come with a high level of risk, there is a need for direct physician supervision; the administration of chemotherapy drugs requires a higher level of work for both the physician and the clinical staff. Also, because of the greater level of risk to the patient and to the provider administering the medication, the code 96413 has a higher non-facility relative value unit (RVU) total 4.21 compared with that of 96365 codes, which have a RVU total 2.22. Both 96413 and 96401 include longer clinical staff times. RVUs are used to determine the Medicare Fee for Service Fee Schedule for Medicare Part B and are the standard in commercial fee schedules, as well. It is the position of the ACR that code 96413 for infusion and 96401 for injection are the appropriate codes for administration of complex biologics.

It is the supervising provider's responsibility to select codes according to current CPT, ICD and HCPCS guidelines for the services and medications rendered for all claims submission. Providers are required to follow the Medicare Modernization Act and comply with current AMA CPT Guidelines for billing, medications and administration codes. Providers should bill consistently according to these guidelines for all payers.

ADMINISTERING BIOLOGICS IN MEDICAL SETTINGS

Biologics carry a high risk of dangerous adverse and allergic reactions, both at the point of care and remotely. As detailed in peer-reviewed research articles, ACR position papers on biologics, and FDA labeling, direct supervision of the infusion of biologics remains the standard of care for the administration of these medications. The administration of infusible biologics requires a safety checklist and detailed patient history and evaluation prior to their infusion by specially trained providers. Given the black box warnings for serious infusion reactions and infections, the safest location for the administration of these drugs remains a setting supervised by a physician. The clinical monitoring is best accomplished and risks are best mitigated when these drugs are infused in medical facilities rather than at a patient's residence. Given the level of care and required expertise, the position of the ACR is that proper administration of biologics should take place under the close supervision of a physician. Biologics should be given in a physician's office or medical facility whenever possible to ensure the highest standards of safety for patients. Financial matters related to potential cost savings of home infusions should not override the safety of the patients and standards of practice.

Biologics are currently administered and coded according to the CPT manual, and in accordance with this definition, these agents require direct physician supervision. Thus, not only does the ACR recognize the safest standards of practice, the AMA and CPT have defined the coding regulations requiring oversight by a physician. Again, managed plans and specialty pharmacies should comply with coding regulations set forth by these associations.

There may be rare circumstances in which home infusions could be medically necessary in order for a particular patient to have access to treatment with a biologic. In these highly unusual situations, the increased risk of a home infusion may be outweighed by the risks associated with a lack of access to biologic therapy at all. The ACR encourages providers in such unusual and difficult situations to make the best medical decision based on the individual needs of the patient. The ACR believes that home infusion for the sake of cost-cutting undermines patient safety. Home infusion of biologics is considered an unnecessary and dangerous risk to patients and violates our current clinical standards of practice.

In addition to the safety considerations and compliance issues, forcing patients to perform infusions at home inadvertently threatens to reduce access to these critical therapies. Specialty trained physicians are less likely to prescribe treatments that are not administered properly in the safest clinical setting for their patients.

ECONOMIC CHALLENGES OF BIOLOGICS

Biologic therapies are a leading cost in health care.[16] Biologic therapies, on the other hand, prevent the costly outcomes of uncontrolled arthritis including cumulative steroid toxicities, extensive diagnostic testing, orthopedic and surgical procedures, disabilities, or other possible downstream comorbid outcomes.[2] Cost considerations for both the patient and payer are a crucial component in medical decision making. Thus, providers consider and document both the medical indications and clinical rationale of the chosen drug as a part of medically reasonable criteria. Since third parties outside the patient-doctor relationship may be neither responsible nor liable for the consequences of these decisions, they should not determine the choice of biologic.

The Patient Protection and Affordable Care Act of 2010 strives for more conservative spending and improved access to medical treatments in an attempt to improve the well being of the patient and lower health care expenditures. At present, there are many stakeholders who influence access to medically necessary treatments: providers, consumers, government and industry. There is an ongoing debate regarding what constitutes “affordable” and “medically necessary.”[17] The result is inconsistent policies in coverage and payment for biologics. For instance, private insurance companies have developed step or “fail first therapy” policies based on privately negotiated special pricing to the insurance company. These policies often undermine access to the most effective treatment option for the patient. While there is cost savings to the insurance company, overall spending for the health care system remains the same.

According to the CMS manual and guidelines, medical necessity should not be based on payment policies, although considerations have been made where treatments had added cost value. Some treatments, such as certain biologic therapies, may actually improve the cost effectiveness compared to alternative therapies. In the past, special considerations have been made by contractors where the therapy will actually result in lowered cost compared to covered alternatives. For example, a part D injectable biologic overall costs less than a part B infusion biologic but the higher out of pocket expense of part D therapies prevents most Medicare patients from accessing any part D biologic options. Thus Medicare contractors may demonstrate lowered

spending by restricting access to part D biologics but inadvertently raise spending by cost shifting to part B expenditures.

Expenses incurred by patients, insurers, providers and the greater health system must be considered in the context of the high value of biologic therapy for individual patients and society as a whole. Given the value of biologic therapies to patients who require these treatments, the ACR believes that policies related to biologic access to treatment should be transparent and prioritize the well being and health of patients.[18]

RESOURCES

1. Singh JA, Furst DE, Bharat A, Curtis J, Kavanaugh A, Kremer J, et al. 2012 Update of the 2008 Recommendations for the use of Disease-Modifying Anti-Rheumatic Drugs and Biologics in the treatment of Rheumatoid Arthritis. Arthritis Care Res 2012;64:625-39.
2. Cush JJ. Early Rheumatoid Arthritis: is there a window of opportunity? J Rheumatol Suppl 2007;80:1-7.
3. Brennan A, Bansback N, Nixon R, Madan J, Harrison M, Watson K, et al. Modelling the cost effectiveness of TNF-alpha antagonists in the management of rheumatoid arthritis: results from the British Society for Rheumatology Biologics Registry. Rheumatology 2007;46:1345–54.
4. Vermeer M, Kievit W, Kuper HH, Braakman-Janse LM, Bernelot Moens HJ, Zijlstra TR et al. Treating to the target of remission in early rheumatoid arthritis is cost-effective: results of the DREAM registry. BMC Musculoskelet Disord 2013;14:350.
5. American College of Rheumatology's Part B Biologic Access and Medical Necessity. 2013.
6. American College of Rheumatology's Patient Access to Biologics Policy. 2015. http://www.rheumatology.org/Practice/Clinical/Drugsafety/Drug_Safety_(Members__Only].
7. Hmiel LK, Brorson KA, Boyne MT. Post-translational structural modifications of immunoglobulin G and their effect on biological activity. Anal Bioanal Chem 2015;407:79-94.
8. Schiestl M, Stangler T, Torella C, Cepeljnik T, Toll H, Grau R. Acceptable changes in quality attributes of glycosylated biopharmaceuticals. Nat Biotechnol 2011;29:310–2.
9. Dorner T, Strand V, Castaneda-Hernandez G, Ferracciolo G, Isaacs JD, Kvien TK, et al. The role of biosimilars in the treatment of rheumatic diseases. Ann Rheum Dis 2013;72:322–8.
10. Weinblatt ME, Kremer JM, Bankhurst AD, Bulpitt KJ, Fleischmann RM, Fox RI, et al. A trial of etanercept, a recombinant tumor necrosis factor receptor:Fc fusion protein, in patients with rheumatoid arthritis receiving methotrexate. N Engl J Med 1999;340:253-9.
11. Cheifetz A, Smedley M, Martin S, Reiter M, Leone G, Mayer L, Plevy S. The incidence and management of infusion reactions to infliximab: a large center experience. Am J Gastroenterol 2003;98:1315-24.
12. Reggia R, Franceschini F, Tincani A, Cavazzana I Switching from intravenous to subcutaneous formulation of abatacept: a single-center Italian experience on efficacy and safety. J Rheumatol. 2015 Feb;42(2):193-5
13. CMS Chapter 12 30.5 CMS Chapter 12 Section 30.5 - 30.5 - Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions. Rev. 968. Issued: 05-26-06; Effective: 06-26-06.
http://www.rheumatology.org/CMS_Chapter_12_Section_30_5.pdf
http://www.rheumatology.org/ACA_and_Medical_Necessity.pdf

14. CPT Manual Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Adminsitration (96401-96549)
15. A Rheumatologist's Dilemma – 96372 vs. 96401. (2011, December). *The Rheumatologist*. http://www.the-rheumatologist.org/details/article/1421247/A_Rheumatologists_Dilemma96372_vs__96401.html.
16. Evaluate World Preview 2014, Outlook to 2020.
17. Skinner, D. Defining Medical Necessity under the Patient Protection and Affordable Care Act. Public Administration Review 2013;73:S49-59.
18. American College of Rheumatology Position Statement on Step Therapy. http://www.rheumatology.org/Practice/Clinical/Position/Position_Statements/.

AMERICAN COLLEGE RHEUMATOLOGY

SUBJECT:	Part B Biologic Access and Medical Necessity
PRESENTED BY:	Committee on Rheumatologic Care
FOR DISTRIBUTION TO:	Providers and Members of the ACR Medical Societies Members of Congress Medicare Administrative Contractors (MACs) Centers for Medicare and Medicaid Services (CMS)

BACKGROUND

Beginning in September 2013, several Medicare Administrative Contractors (MACs) attempted to exclude Part B coverage for certolizumab, abatacept, and golimumab. They determined that these three physician administered biologics on their part B formulary could be relegated to a self administration drug (SAD) list. In response to advocacy efforts of the ACR, state rheumatology societies, the Arthritis Foundation, members of Congress, and other affected entities, they reconsidered their decision. Along with the Centers for Medicare and Medicaid Services (CMS), they concluded that the intravenous and subcutaneous formulations are separate and distinct medications and issued an update covering the physician administered medications under part B benefits. The ACR agrees with CMS that these drugs should be covered when the conditions for coverage are met and when their use is medically necessary. Since CMS recognizes the medical necessity of these biologic medications for the treatment of arthritis and rheumatic diseases, this paper will define the reasonable and necessary criteria for treatment for all biologic agents.

MEDICAL NECESSITY DOCUMENTATION

In accordance with existing CMS guidelines[1] and in order to avoid denial of claims for part B therapies, documentation should include sufficient, accurate information to support 1) the diagnosis of arthritis, 2) the justification of treatment choice, and 3) document the course of and response to therapy.

1) DIAGNOSIS. Rheumatic diseases are complex systemic illnesses. The medical record should reflect the diagnosis of the rheumatic condition by the treating physician.
2) JUSTIFICATION OF TREATMENT CHOICE.
   A. Biologics are indicated in patients with active disease who fail methotrexate or other non-biologic disease modifying anti-rheumatic drugs (DMARDs). Failing non-biologic DMARD therapy includes medication intolerance, inadequate response, or contraindication to DMARDs. Failing conventional treatment for rheumatic conditions may also include other immunomodulating therapies or NSAIDs. Physical function, extent of disease, prevention of damage, and signs and symptoms of active disease should be considered in determining treatment in accordance with FDA indications and labeling.[2,3]

   B. There are rapidly changing advancements in rheumatic diseases that give rise to complex medical decision making regarding biologic treatment choices. Biologics vary in molecular structure, mode of action, indications, route of administration, frequency of administration, pharmacokinetics, tolerability, and efficacy in individual patients. Treating physicians determine the choice of biologic therapy according to the medical factors in each patient's case.

Unique clinical circumstances for each patient will guide the medical decision process. Examples of medical factors that determine the choice of drug and route of administration include age of the patient, duration of the disease, extent of disease, physical limitations, extra-articular manifestations, comorbid conditions, and overlap with other rheumatologic conditions.
Indications for a particular drug may vary based on bioavailability factors and flexibility in administration. For example, due to their own medical condition, patients may require administration assistance, close supervision, or more frequent observation during their treatments. The lyopholized and intravenous preparations, according to FDA labeling, require specialized preparation and administration under the supervision of a physician. Of important note, intravenous therapies may be more efficacious in certain patients since these drugs can be adjusted by dosage and frequency of administration. Given their differences in FDA indications, pharmacokinetic characteristics, dosing regimens (weight based dosing vs. flat dosing), indications, and clinical data, these drugs are not equivalent to those preparations already approved for self administration. In patients who require physician supervision, part B biologics may be medically necessary to ensure both clinical effectiveness and safety for the patient.

Previous allergic or infusion reactions, painful injections or infusions, an individual's infection risk, and other safety concerns amongst the different methods of delivery also influence the doctor's choice of biologic. The clinical response as well as adverse effects of any biologic will vary by individual patient. Thus, a patient relies on the specialized training and experience of the treating rheumatologist to determine the most reasonable, medically necessary treatment. In order to make an appropriate medical decision, the rheumatologist follows the standards of medical practice and incorporates the patient's unique medical history.

3) MAINTENANCE OF THERAPY.

Rheumatic conditions are chronic diseases that require ongoing medical services and treatment. In a treat to target era, Rheumatologists must monitor for clinical progress, responses to therapy, and patient safety. Biologics are critical therapies that are chosen to prevent joint damage and further loss of function and to achieve either remission or low disease activity. In the absence of remission, demonstrating clinical improvement, tolerability, and safety remain forefront goals of treatment. However, maintenance of current functional abilities, prevention of further deterioration, and patient education are appropriate concomitant treatment goals and should justify coverage for ongoing therapy.

For patients who achieve progress on a particular medication, it remains standard of care to continue therapy. The ACR opposes forcing patients off stable therapy. In addition to the health threats of uncontrolled disease, switching and interrupted biologic therapies pose unique risks including possible immunologic adverse events, such as new allergic reactions and loss of efficacy of previous therapy. Moreover, cessation of stable therapy leads to increased flares, disease burden, and increased morbidity and mortality. The ACR asserts that patients in whom documentation of satisfactory clinical improvement, disease stability, safety, and tolerability have been provided should not be required to change therapies. Ongoing treatment is medically
appropriate and these clinical goals align with the CMS guidelines for claims for chronic services.

COST EFFECTIVENESS

According to the CMS manual and guidelines, medical necessity should not be based on payment policies, although considerations have been made where treatments had added cost value.[1] Some treatments, such as certain biologic therapies, may actually improve the cost effectiveness compared to alternative therapies. For example lyophilized certolizumab may be medically necessary and reduce cost compared to infusion therapies. In the past, special considerations have been made by contractors where the therapy will actually result in lowered cost compared to covered alternatives. For example, The Notice of Intent raised the issue that there are therapies that improves diagnosis and treatment, improves function of a patient, and improves overall "health outcomes."[1]

In addition to qualifying as medically necessary treatments, biologic therapies prevent the costly outcomes of uncontrolled arthritis, including cumulative steroid toxicities, unnecessary diagnostic imaging, orthopedic and surgical procedures, disabilities, or other possible downstream comorbid outcomes. In some cases, a certain biologic may cost less than another therapy and may be chosen for both clinical effectiveness and for cost advantages. Thus, providers may document both the medical indications and cost effectiveness of the chosen drug.

In summary, the Part B biologic therapies are 1) separate and distinct medications with their own unique properties, 2) safe and effective, 3) appropriate for the treatment of rheumatic conditions and 5) necessary for quality outcomes including prevention and stabilization of chronic, disabling diseases.

REFERENCES

1. Medicare Program Integrity Manual. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.html. Accessed January 31, 2015.
2. Singh JA, Furst DE, Bharat A, Curtis J, Kavanaugh A, Kremer J, et al. 2012 Update of the 2008 Recommendations for the use of Disease-Modifying Anti-Rheumatic Drugs and Biologics in the treatment of Rheumatoid Arthritis. Arthritis Care Res 2012;64:625-39.
3. American College of Rheumatology's Model Biologics Access Policy. 2013. http://www.rheumatology.org/Practice/Clinical/Drugsafety/Drug_Safety_(Members__Only].