

BIOLOGICS, BIOSIMILARS*, AND NON-BIOLOGICS

(Updated 11/27/2024)

I. CODE OF FEDERAL REGULATIONS

67.113(b)(c); 67.213(b)(c); and 67.313(b)(c)

II. MEDICAL HISTORY: Item 48. General Systemic

The individual should provide history as to why the medication is used. If taken for a specific condition, see that section. The AME should inquire when medication was started and if the individual has ever experienced any side effects that could interfere with aviation safety.

III. AEROMEDICAL DECISION CONSIDERATIONS:

See Item 48. General Systemic

IV. PROTOCOL: None

V. PHARMACEUTICAL CONSIDERATIONS

- The underlying condition must be acceptable.
- Observation times: Require ground trial and/or no-fly after each dose.
 - Initial observation: 2-week no-fly/ground trial to verify no side effects.
 - Post-dose observation time (no-fly time): See table.
 - Changing from one biologic/biosimilar to another for the same indication requires forty-eight (48) hour ground trial to mitigate any aeromedical risk.
- 61.53 applies if any adverse change in condition or adverse medication side effect requiring medical attention.

***Note:** Biologics do not have generic medication; they have biosimilar.

See Pages 2 and 3 for a table of medications by name.

CACI ACCEPTABLE BIOLOGICS MEDICATION

As a single agent. For underlying condition(s), see those pages.

Medication Drug Class	
Biologic Medications	Post-dose Observation No-Fly times
B-Cell Inhibitors <ul style="list-style-type: none"> rituximab (Rituxan) 	72 hours
Selective Co-stimulation Modulator <ul style="list-style-type: none"> abatacept (Orencia) 	24 hours
Tumor Necrosis Factor (TNF) Blocking Agent <ul style="list-style-type: none"> infliximab (Inflectra; Remicade; Renflexis) 	24 hours
Tumor Necrosis Factor (TNF) Blocking Agent <ul style="list-style-type: none"> adalimumab (Humira and FDA approved biosimilars) certolizumab (Cimzia) etanercept (Enbrel) golimumab (Simponi) 	4 hours
Interleukin Inhibitor <ul style="list-style-type: none"> anakinra (Kineret) guselkumab (Tremfya) ixekizumab (Taltz) risankizumab (Skyrizi) sarilumab (Kevzara) secukinumab (Cosentyx) tildrakizumab (Ilumya) tocilizumab (Actemra) ustekinumab (Stelara) <ul style="list-style-type: none"> Warn for posterior reversible encephalopathy syndrome (PRES) 	4 hours
Selective Adhesion-Molecule (SAM) Inhibitor <ul style="list-style-type: none"> vedolizumab (Entyvio) 	4 hours
Non-Biologic Medications	Post-dose Observation No-Fly times
Kinase Inhibitor <ul style="list-style-type: none"> baricitinib (Olumiant) tofacitinib (Xeljanz) upadacitinib (Rinvoq) <p>Warn cardiovascular events and clots for all</p>	None
Phosphodiesterase-4 Enzyme Inhibitor <ul style="list-style-type: none"> apremilast (Otezla) <ul style="list-style-type: none"> Report any signs of depression 	None

CONDITIONALLY ACCEPTABLE BIOLOGIC MEDICATIONS WITH SI

As a single agent.

Medication Drug Class	
Biologic Medications	Post-dose Observation No-Fly times
Interleukins <ul style="list-style-type: none">• benralizumab (Fasenra)• dupilumab (Dupixent)• mepolizumab (Nucala)• reslizumab (Cinqair)• tezepelumab (Tezspire)	4 hours
Monoclonal Antibody <ul style="list-style-type: none">• omalizumab (Xolair)	24 hours
Interleukin Inhibitor <ul style="list-style-type: none">• brodalumab (Siliq)• canakinumab (Ilaris)• rilonacept (Arcalyst)	4 hours
Selective Adhesion-Molecule Inhibitor <ul style="list-style-type: none">• natalizumab (Tysabri)<ul style="list-style-type: none">▪ REMS program (due to the risk of progressive multifocal leukoencephalopathy [PML])	48 hours