

Monoclonal Antibodies

The USAN Program and INN Experts are revising the monoclonal antibody nomenclature scheme. The USAN Council sees a need to introduce greater variation in the suffixes of monoclonal antibody names. Over 350 monoclonal antibodies have been named, and dozens have been marketed. This means there are many names ending in –mab and has increased the odds that 2 monoclonal antibody names will look alike. More variation in the names is needed to avoid look-alike, sound-alike medication errors and improve patient safety.

Thus, the USAN Council is eliminating the source infix to shorten the number of required, or fixed, syllables in the name. This should allow more opportunities to vary monoclonal antibody names, reducing the risk of look-alike, sound-alike drug name errors.

There have been disagreements about how source infixes should be defined or assigned involving firms, the USAN Council and the INN Experts. Removing the source infix alleviates delays caused by disagreements over source infix assignment.

This page outlines the updated scheme and supersedes the previous monoclonal antibody nomenclature scheme. It also explains the use of 2-word names for monoclonal antibodies.

Download the Previous Monoclonal Antibodies Policy (PDF).

The Council has no plans to retroactively change names already coined. They believe that changing existing names would confuse physicians, other health care professionals and patients.

Firms should note that nomenclature practices are continually evolving. Further updates may occur any time the Council believes changes are necessary. The USAN Council may later choose to incorporate additional infixes based on mechanism of action, to introduce more variation in the names of monoclonal antibodies.

Conjugated Monoclonal Antibody Naming Policy (Effective Jan. 1, 2019)

USAN Application Flowchart

Effective Jan. 1, 2019 firms can only request a USAN modified for salts or esters of substance that

have already received a USAN (or for which a USAN application has been submitted) and that do not have a peptide or nucleotide sequence. Substances that are not salts or esters but are related require additional work for chemical review and/or Council balloting. Consequently, related compounds that are not salts or esters are treated as single entities. Examples include stereoisomers or enantiomers isolated from a racemic mixture, antibody-drug conjugates, oligonucleotides or other substances where the chemical structure or sequence have changed and another name is required.

The USAN Program is often asked which form to fill out in specific situations.

- | For a small molecule and its salt or ester, please use form A.
- | For all substances for which there is a DNA, RNA or amino acid sequence, please use form F. When more than one name is requested, a separate form F should be filled out for each substance. Therefore, for example, an antisense oligonucleotide and its salt, or an antibody and an antibody-drug conjugate would require two applications using form F.
- | Firms needing to revise the chemical, company, indication or other information associated with a substance should use form D.
- | For a second name for the salt or ester of a substance that already has a USAN (or for which a USAN has been requested), form C should be used.
- | For contact lens polymers, form E should be used.

Elements of a Name

The suffix "-mab" is used for monoclonal antibodies, antibody fragments and radiolabeled antibodies. For polyclonal mixtures of antibodies, "-pab" is used. The -pab suffix applies to polyclonal pools of recombinant monoclonal antibodies, as opposed to polyclonal antibody preparations isolated from blood. This differentiates polyclonal antibodies from individual monoclonal antibodies named with -mab.

In combination products where 2 or more antibodies are manufactured separately and then mixed, each component receives a separate USAN ending in –mab.

Sequence of Stems and Infixes

The key elements of a monoclonal antibody name appear in the following order:

1. Prefix
2. Infix representing the target
3. Stem used as a suffix (-mab or –pab)

Prefix

To create a unique name, a distinct, compatible syllable or syllables should be selected as the prefix.

Suggested prefixes should comply with the USAN Program's rules for coining names. In addition, we ask that manufacturers avoid potential conflicts with names of other monoclonal antibodies. Although it is desirable for names to be as short as possible, a prefix that is 2 or more syllables long may be necessary to distinguish the name from those previously assigned.

Target Infix

The target infix places information about the action or use of the antibody in the name. The USAN Council has approved specific syllables to denote diseases or targets. Additional target infixes may be added to the scheme if the USAN Council believes there is sufficient rationale to do so.

The choice of infix is determined by the available information regarding initial clinical indications and antibody action. The Council may request more details and evidence regarding antibody action and indications.

Target Infixes for Monoclonal Antibodies

A definition and an example of use are provided for the following infixes:

-ami- = Serum amyloid protein (SAP) as in -amimab

-ba- = Bacterial as in -bamab

-ci- = Cardiovascular as in -cimab

-d(e) = Endocrine targets -demab

-fung- = Antifungal as in -fungmab

-gros- = Skeletal muscle mass related growth factors and receptors as in -grosrab

-ki- = Interleukins as in -kimab

-li- = Immunomodulating as in -limab

-ne- = Neural as in -nemab

-os- = Bone as in -osmab

-ta- = Tumors as in -tamab

-toxa- = Toxin target as in -toxamab

-vet-* = Veterinary use as in -vetmab

-vi- = Viruses, antiviral indications as in -vimab

*An additional infix may be used with –vetmab to further specify the indication or target.

USAN Modified Designations for Monoclonal Antibodies

Sometimes the name of a monoclonal antibody requires additional clarifying words.

If the antibody is conjugated to a payload, such as radiolabel or toxin, this conjugate is identified by using a separate, second word or other acceptable chemical designation. For antibodies conjugated to a toxin, the "-tox" stem must be included as part of the name selected for the toxin (e.g., zolimomab aritox, in which aritox identifies ricin A-chain). In other cases (e.g., brentuximab vedotin), the payload may receive a name based on a stem or a chemical name.

For radiolabeled products, the word order is:

1. Name of the isotope
2. Element symbol
3. Isotope number
4. Name of the monoclonal antibody, as follows:

| technetium Tc 99m biciromab
| indium In 111 altumomab pentetate

The "peg-" prefix may be used for pegylated mAbs, but it should be avoided if it leads to an overly long name. Usually a 2-word name is preferable with the first word referring to the monoclonal antibody and "pegol" as the second word.

When firms apply to name an antibody conjugated to a payload, they should file separate USAN

applications for the antibody and the payload, as well as the application for the conjugate. This allows the USAN Council to assign separate USAN designations to each component. The USAN Modified Application may be used for the additional names.

Download the USAN Requirements for Monoclonal Antibodies (PDF).