

Table of Contents

Welcome to CTCAE Dictionary	1
Searching the CTCAE Dictionary	1
Additional Guidelines and Resources.....	1
Search CTCAE Dictionary by Category.....	1
Search the CTCAE Dictionary Using the Literal Button.....	2
Search the CTCAE Dictionary Using the Keyword Button.....	3
When and How to Use the <i>Other, specify</i> Mechanism	4
Adverse Event Reporting Resources	5
Expedited Adverse Event Reporting.....	5
NCI CTEP Help Desk.....	5

Welcome to CTCAE Dictionary

The CTCAE Dictionary enables clinical trials researchers to access the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) grading criteria at point of care.

The application provides quick access to the CTCAE Dictionary and allows you to search by adverse events by category, index, or keyword.

Searching the CTCAE Dictionary

[Search the CTCAE Dictionary by category](#)

[Search the CTCAE Dictionary Using the Literal Button](#)

[Search the CTCAE Dictionary Using the Keyword Button](#)

Additional Guidelines and Resources

[When and How to Use the *Other, Specify Mechanism*](#)

[Adverse Event Reporting Resources](#)

[Adobe Acrobat Reader](#)

Search CTCAE Dictionary by Category

1. Access the CTCAE Dictionary by logging on to the application and selecting the **Dictionary** tab.

2. To display a list of adverse events for a category, select the category from the [CATEGORY drop-down list](#).

This displays a list of adverse events (by short name) as hyperlinks.

3. For information on an adverse event, click its hyperlink to see the category, full name, MedDRA code, grades, description, and (where applicable) supra-ordinate terms, remarks, and terms also to consider.

Note: Any *Other, specify* terms that are part of the search results are displayed at the bottom. For more information, see [When and How to Use the Other specify Mechanism](#).

4. To limit the search results alphabetically, click one of the [alphabet buttons](#) (that is, **#ab, cde, fgh, ijk, lmn, opq, rst, uvw, or xyz**) below the **Search for** field or within the adverse event details (where applicable).



The system highlights the selected button in yellow. The default is to view **all** results.

Search the CTCAE Dictionary Using the Literal Button

Literal searches are full text searches for a specific word. Literal searches return Adverse Events (AEs) that have the searched-for word in at least one of the following places:

- Adverse Event
- Category
- Short name
- Grade description
- Remarks

Example:

If you need to know the MedDRA code for pain but you aren't sure which disorder you want to use, in the Enter Search Criteria screen, click **all** in the row of alphabetical groupings. In the **Search for** field, enter the word *pain*. Click **Literal**. The following appears.

The screenshot shows the SAFETY profiler interface for 'Common Terminology Criteria for Adverse Events v4.0'. The search criteria are set to 'All Categories' and 'pain'. The search results are displayed in a table with two columns: 'Adverse Event' and 'CATEGORY'.

Adverse Event	CATEGORY
Abdominal pain	Gastrointestinal disorders
Anal pain	Gastrointestinal disorders
Arthralgia	Musculoskeletal and connective tissue disorders
Arthritis	Musculoskeletal and connective tissue disorders
Back pain	Musculoskeletal and connective tissue disorders
Bone pain	Musculoskeletal and connective tissue disorders
Breast pain	Reproductive system and breast disorders
Bullous dermatitis	Skin and subcutaneous tissue disorders
Buttock pain	Musculoskeletal and connective tissue disorders
Chest pain - cardiac	Cardiac disorders
Chest wall pain	Musculoskeletal and connective tissue disorders
Colitis	Gastrointestinal disorders
Dyspareunia	Reproductive system and breast disorders
Ear pain	Ear and labyrinth disorders

You locate the AE you want, for example, *buttock*. Click on it to find the MedDRA code for the AE (in this case, 10048677). You have found the desired information.

To conduct a Literal search, do the following:

1. Access the CTCAE Dictionary by logging on to the application and selecting the **Dictionary** tab.
By default, the system displays the search page for the current CTCAE version. To access search pages for earlier versions, select the appropriate tab.
2. To display a list of adverse events for an index term, enter the term in the **Search for** field and click the **Literal** button.
This displays a list of adverse events (by short name) as hyperlinks.
3. For information on an adverse event, click its hyperlink to see the category, full name, MedDRA code, grades, description, and (where applicable) supra ordinate terms, remarks, and terms also to consider.
Note: Any *Other, specify* terms that are part of the search results are displayed at the bottom. For more information, see [When and how to use the Other, specify mechanism](#).
4. To limit the search results alphabetically, click one of the **alphabet buttons** (that is, **#ab, cde, fgh, ijk, lmn, opq, rst, uvw, xyz**) below the **Search for** field or within the adverse event details (where applicable).



The system highlights the selected button in yellow. The default is to view **all** results.

Search the CTCAE Dictionary Using the Keyword Button

Keyword searches are more sophisticated than Literal searches. The actual word (e.g., Muscular weakness) may not appear in any of the locations required for Literal searches (Adverse Event, Category, Short Name, Grade description, or Remarks). However, the search returns any AEs related to the Keyword.

Example:

If you want to compare information on one muscular weakness with another, use the Keyword search. In the Enter Search Criteria screen, click **all** in the row of alphabetical groupings. In the **Search for** field, enter the word *muscular weakness*. Click **Keyword**. The following appears.

Enter Search Criteria

CATEGORY: All Categories

Search for: Muscular weakness Literal **Keyword**

#ab cde fgh ijk lmn opq rst uvw xyz **all**

Adverse Event	CATEGORY
Generalized muscle weakness	Musculoskeletal and connective tissue disorders
Muscle weakness left-sided	Musculoskeletal and connective tissue disorders
Muscle weakness lower limb	Musculoskeletal and connective tissue disorders
Muscle weakness right-sided	Musculoskeletal and connective tissue disorders
Muscle weakness trunk	Musculoskeletal and connective tissue disorders
Muscle weakness upper limb	Musculoskeletal and connective tissue disorders

Adverse Event Details

CATEGORY: Musculoskeletal and connective tissue disorders

Adverse Event: Generalized muscle weakness

Short Name: Generalized muscle weakness

MedDRA Code: 10062572

Grade	Description
1	Symptomatic; weakness perceived by patient but not evident on physical exam
2	Symptomatic; weakness evident on physical exam; weakness limiting instrumental ADL
3	Weakness limiting self care ADL; disabling

* MedDRA Version 12.0

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Questions/Help: email: ncictephhelp@ctep.nci.nih.gov

Now, with all the disorders related to muscular weakness listed, you can easily compare them.

To conduct a Keyword search, do the following:

1. Access the CTCAE Dictionary by logging on to the application and selecting the **Dictionary** tab.

By default, the system displays the search page for the current CTCAE version. To access the search pages for earlier versions, select the appropriate tab.

2. To display a list of adverse events for a keyword, enter the keyword in the **Search for** field and click the **Keyword button**.

This displays a list of adverse events (by short name) as hyperlinks.

3. For information on an adverse event, click its hyperlink to see the category, full name, MedDRA code, grades, description, and (where applicable) supra ordinate terms, remarks, and terms also to consider.

Note: Any *Other, specify* terms that are part of the search results are displayed at the bottom. For more information, see [When and how to use the Other, specify mechanism](#).

4. To limit the search results alphabetically, click one of the **alphabet buttons** (that is, **#ab, cde, fgh, ijk, lmn, opq, rst, uvw, or xyz**) below the **Search for** field or within the adverse event details (where applicable).



The system highlights the selected button in yellow. The default is to view **all** results.

When and How to Use the *Other, specify Mechanism*

The Common Terminology Criteria for Adverse Events (CTCAE) is a standardized terminology and grading system for adverse event (AE) reporting. The use of CTCAE allows investigators, trial sponsors (CTEP), and

regulatory agencies (FDA) to assess and evaluate AEs to assure patient safety. CTCAE was designed to be as comprehensive as possible. In recognition that as science and cancer treatments continue to evolve and the potential for novel and unknown untoward affects to occur, the NCI has incorporated a mechanism into CTCAE to capture these yet-to-be-defined events.

In the rare event that a suitable CTCAE term cannot be found, the NCI allows the submitter to report the appropriate verbatim term via the *Other, specify* mechanism. The use of the *Other, specify* mechanism is an exception, not the rule. All AEs must be documented in the source documentation (i.e., patient chart). As per regulation, the investigator (physician) is responsible for reporting AEs to the study sponsor (i.e., the CTEP, NCI). If a suitable CTCAE term is not available, the investigator must make a note to this affect in the source documentation. In addition, the investigator should identify the most appropriate CTCAE CATEGORY to classify the event.

A CTCAE CATEGORY is a broad classification of AEs based on anatomy and/or pathophysiology (for example, cardiac disorders; gastrointestinal disorders). Within each CATEGORY is a CTCAE term *Other* (i.e., Gastrointestinal disorders– *Other, specify*). If one of the CTCAE CATEGORY *Other* terms is selected, then the submitter must describe or *specify* what the adverse event was. The description must be explicit and provide sufficient detail to describe the event. The descriptions should be as brief as possible (for example, two-to-four words).

Once the CTCAE CATEGORY *Other* term has been selected and specified, the submitter must 'Grade' the event. The grade refers to the severity of the event. The grades to be used for the *Other, specify* mechanism are as follows:

- Grade 1 – Mild AE
- Grade 2 – Moderate AE
- Grade 3 – Severe AE
- Grade 4 – Life threatening or disabling AE
- Grade 5 – Death related to AE

To minimize overuse, CTEP, NCI will build rules into the CDUS Smart-loader to flag and/or reject reports that take excessive advantage of the 'Other, specify' mechanism. In addition, CTEP, NCI will closely scrutinize all AEs submitted as 'Other, specify'. The investigator will be required to correct and resubmit the CDUS report if a suitable CTCAE term is identified by CTEP, NCI staff.

Adverse Event Reporting Resources

[Common Terminology Criteria for Adverse Events \(CTCAE\) Current Version](#)

[Expedited Adverse Event Reporting](#)

[NCI CTEP Help Desk](#)

Expedited Adverse Event Reporting

The [CTEP Adverse Event Reporting System \(CTEP-AERS\) Web page](#) includes the following information and tools:

- [NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD \(CTEP and CIP\) and DCP INDs and IDEs](#)

NCI CTEP Help Desk

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