

## Common Terminology Criteria for Adverse Events (CTCAE) v3.0 Notice of MedDRA Code Modifications, December 12, 2003

The table below provides the MedDRA v6.0 and provisional codes for the *Select* AEs added to the *CTCAE v3.0*  
*Publish Date: December 12, 2003.*

Supra-ordinate term and Select AE	MedDRA Code and Preferred Term or Provisional Code
INFECTION Infection with unknown ANC – <i>Select</i> ; 'Blood' (within the 'GENERAL' Subcategory)	10040050 (Sepsis NOS)
INFECTION Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils – <i>Select</i> ; 'Blood' (within the 'GENERAL' Subcategory)	90030984 (Provisional)
INFECTION Infection with normal ANC or with Grade 1 or 2 neutrophils – <i>Select</i> ; 'Blood' (within the 'GENERAL' Subcategory)	90030986 (Provisional)

The table below details the revisions made to the MedDRA v6.0 codes listed in the *CTCAE v3.0 Effective October 1, 2003* and *CTCAE v3.0 (with Grades) Effective October 1, 2003* comma delimited text (.txt) files since their initial publication on June 10, 2003. The files have been updated and posted to the CTEP List of Codes and Values Web page at <http://ctep.cancer.gov/guidelines/codes.html#imt>.

Revision to	V6.0 MedDRA code included in the June 10, 2003 comma delimited files	Revised MedDRA Code and Preferred Term or Provisional Code
AUDITORY/EAR Otitis, external ear (non-infectious)	90030000	10052558 (Otitis externa NOS)
INFECTION Infection with normal ANC or Grade 1 or 2 neutrophils – AUDITORY/EAR, External ear (otitis externa)	10052558	90030319 (Provisional)
INFECTION Infection w/ normal ANC or Grade 1 or 2 neutrophils – GENERAL, Catheter-related	10007810	90030309 (Provisional)
INFECTION Infection with normal ANC or Grade 1 or 2 neutrophils – GENERAL, Wound	10048038	90030351 (Provisional)
INFECTION Infection with unknown ANC – AUDITORY/EAR, External ear (otitis externa)	90030390	10014012 (Ear infection NOS)
INFECTION Infection with unknown ANC – GENERAL, Catheter-related	90030372	10007810 (Catheter-related infection)
INFECTION Infection with unknown ANC – GENERAL, Wound	90030502	10048038 (Wound infection)
SYNDROMES Syndromes – Other (Specify, __)	90030954	90004094 (Provisional)

