

S4 Table. List of MedDRA preferred terms included in clustered terms^{a)}

Clustered term	MedDRA preferred terms included
PROFILE 1007	
Abdominal pain	Abdominal discomfort; abdominal pain; abdominal pain lower; abdominal pain upper; or abdominal tenderness
Anemia	Anemia; anemia macrocytic; anemia megaloblastic; hemoglobin; hemoglobin decreased; hyperchromic anemia; hypochromic anemia; hypoplastic anemia; microcytic anemia; or normochromic normocytic anemia
ALT increased	Alanine aminotransferase; alanine aminotransferase abnormal; or alanine aminotransferase increased
AST increased	Aspartate aminotransferase; aspartate aminotransferase abnormal; or aspartate aminotransferase increased
Chest pain	Chest discomfort; chest pain; musculoskeletal chest pain; or noncardiac chest pain
Cough	Cough; or productive cough
Dizziness	Balance disorder; dizziness; dizziness exertional; dizziness postural; or presyncope
Dyspnea	Dyspnea; dyspnea at rest; dyspnea exertional; dyspnea paroxysmal nocturnal; nocturnal dyspnea; or orthopnea
Edema	Face edema; generalized edema; local swelling; localized edema; edema; edema peripheral; or periorbital edema
Elevated transaminases	Alanine aminotransferase; alanine aminotransferase abnormal; alanine aminotransferase increased; aspartate aminotransferase; aspartate aminotransferase abnormal; aspartate aminotransferase increased; gamma-glutamyltransferase abnormal; gamma-glutamyltransferase increased; hepatic enzyme abnormal; hepatic enzyme increased; hepatic function abnormal; hypertransaminasemia; liver function test abnormal; transaminases; transaminases abnormal; or transaminases increased
Interstitial lung disease	Acute interstitial pneumonitis; acute lung injury; acute respiratory distress syndrome; alveolitis; alveolitis allergic; alveolitis fibrosing; alveolitis necrotizing; diffuse alveolar damage; eosinophilic pneumonia acute; interstitial lung disease;

	pneumonitis; or pulmonary toxicity
Leukopenia	Leukopenia; or white blood cell count decreased
Neuropathy	Acute polyneuropathy; amyotrophy; areflexia; autoimmune neuropathy; autonomic failure syndrome; autonomic neuropathy; axonal neuropathy; biopsy peripheral nerve abnormal; burning feet syndrome; burning sensation; decreased vibratory sense; demyelinating polyneuropathy; dysesthesia; electromyogram abnormal; formication; gait disturbance; genital hypoesthesia; Guillain-Barre syndrome; hyperesthesia; hypoesthesia; hyporeflexia; hypotonia; ischemic neuropathy; loss of proprioception; Miller Fisher syndrome; mononeuritis; mononeuropathy; mononeuropathy multiplex; motor dysfunction; multifocal motor neuropathy; muscle atrophy; muscular weakness; myelopathy; nerve conduction studies abnormal; nerve degeneration; neuralgia; neuritis; neuromuscular toxicity; neuromyopathy; neuropathy peripheral; neuropathy vitamin B ₆ deficiency; neurotoxicity; paresthesia; peripheral motor neuropathy; peripheral nerve lesion; peripheral nerve palsy; peripheral nervous system function test abnormal; peripheral sensorimotor neuropathy; peripheral sensory neuropathy; peroneal muscular atrophy; peroneal nerve palsy; phrenic nerve paralysis; polyneuropathy; polyneuropathy chronic; polyneuropathy idiopathic progressive; radiation neuropathy; sensorimotor disorder; sensory disturbance; sensory loss; skin burning sensation; temperature perception test decreased; Tinel sign; toxic neuropathy; or ulnar neuritis
Neutropenia	Febrile neutropenia; neutropenia; or neutrophil count decreased
Stomatitis	Cheilitis; glossitis; glossodynia; mouth ulceration; mucosal inflammation; oral pain; oropharyngeal discomfort; oropharyngeal pain; or stomatitis
Thrombocytopenia	Platelet count decreased; or thrombocytopenia
Vision disorder	Chromatopsia; diplopia; halo vision; photophobia; photopsia; vision blurred; visual acuity reduced; visual brightness; visual field defect; visual impairment; or vitreous floaters
Upper respiratory infection	Laryngitis; nasopharyngitis; pharyngitis; rhinitis; or upper respiratory tract infection

PROFILE 1014

Abdominal pain	Abdominal discomfort; abdominal pain; abdominal pain lower; abdominal pain upper; or abdominal tenderness
Anemia	Anemia; anemia macrocytic; anemia megaloblastic; hemoglobin; hemoglobin decreased; hyperchromic anemia; hypochromic anemia; hypoplastic anemia; microcytic anemia; or normochromic normocytic anemia
Bradycardia	Bradyarrhythmia; bradycardia; heart rate decreased; sinus arrest; or sinus bradycardia
Chest pain	Chest discomfort; chest pain; musculoskeletal chest pain; or noncardiac chest pain
Cholestasis	Bilirubin conjugated; bilirubin conjugated abnormal; bilirubin conjugated increased; bilirubin excretion disorder; blood bilirubin; blood bilirubin abnormal; blood bilirubin increased; cholestasis; cholestatic liver injury; hepatitis cholestatic; hyperbilirubinemia; jaundice ^{a)} ; jaundice cholestatic; jaundice hepatocellular; mixed liver injury; ocular icterus; or yellow skin
Cough	Cough; or productive cough
Dizziness	Balance disorder; dizziness; dizziness exertional; dizziness postural; or presyncope
Dyspnea	Dyspnea; dyspnea at rest; dyspnea exertional; dyspnea paroxysmal nocturnal; nocturnal dyspnea; or orthopnea
Edema	Edema; edema peripheral; face edema; generalized edema; local swelling; localized edema; or periorbital edema
Elevated transaminases	Alanine aminotransferase; alanine aminotransferase abnormal; alanine aminotransferase increased; aspartate aminotransferase; aspartate aminotransferase abnormal; aspartate aminotransferase increased; gamma-glutamyltransferase abnormal; gamma-glutamyltransferase increased; hepatic enzyme abnormal; hepatic enzyme increased; hepatic function abnormal; hypertransaminasemia; liver function test abnormal; transaminases; transaminases abnormal; or transaminases increased
Esophagitis	Erosive esophagitis; esophagitis; esophagitis hemorrhagic; esophagitis ulcerative; or necrotizing esophagitis

Gastrointestinal perforation	Anastomotic ulcer perforation; diverticular perforation; duodenal perforation; duodenal ulcer perforation; duodenal ulcer perforation, obstructive; esophageal perforation; esophageal rupture; esophageal ulcer perforation; gastric perforation; gastric ulcer perforation; gastric ulcer perforation, obstructive; gastrointestinal anastomotic leak; gastrointestinal perforation; gastrointestinal ulcer perforation; ileal perforation; ileal ulcer perforation; intestinal perforation; intestinal ulcer perforation; jejunal perforation; jejunal ulcer perforation; large intestinal ulcer perforation; large intestine perforation; peptic ulcer perforation; peptic ulcer perforation, obstructive; perforated peptic ulcer oversewing; perforated ulcer; rectal perforation; small intestinal perforation; or small intestinal ulcer perforation
Hepatotoxicity	Acute hepatic failure; cholestatic liver injury; coma hepatic; drug-induced liver injury; hepatic encephalopathy; hepatic failure ^{a)} ; hepatic necrosis; hepatic steatosis; hepatitis fulminant; hepatocellular injury; hepatorenal failure; hepatorenal syndrome; hepatotoxicity; liver disorder; liver injury; mixed liver injury; or subacute hepatic failure
Hypogonadism	Androgen deficiency; blood gonadotropin abnormal; blood gonadotropin decreased; blood gonadotropin increased; blood testosterone abnormal; blood testosterone decreased; blood testosterone free decreased; gonadotropin deficiency; hypogonadism; hypogonadism male; saliva testosterone abnormal; saliva testosterone decreased; or secondary hypogonadism
Interstitial lung disease	Acute interstitial pneumonitis; acute lung injury; acute respiratory distress syndrome; alveolitis; alveolitis allergic; alveolitis necrotizing; diffuse alveolar damage; eosinophilic pneumonia; eosinophilic pneumonia acute; idiopathic pulmonary fibrosis; interstitial lung disease; pneumonitis; or pulmonary toxicity
Leukopenia	Leukopenia; or white blood cell count decreased
Lymphopenia	Lymphocyte count decreased; or lymphopenia
Neuropathy	Acute polyneuropathy; amyotrophy; areflexia; autoimmune neuropathy; autonomic failure syndrome; autonomic neuropathy; axonal neuropathy; biopsy peripheral nerve abnormal; burning feet syndrome; burning sensation; decreased vibratory sense; demyelinating polyneuropathy; dysesthesia; electromyogram abnormal; formication; gait disturbance; genital hypoesthesia;

	Guillain-Barre syndrome; hyperesthesia; hypoesthesia; hyporeflexia; hypotonia; ischemic neuropathy; loss of proprioception; Miller Fisher syndrome; mononeuritis; mononeuropathy; mononeuropathy multiplex; motor dysfunction; multifocal motor neuropathy; muscle atrophy; muscular weakness; myelopathy; nerve conduction studies abnormal; nerve degeneration; neuralgia; neuritis; neuromuscular toxicity; neuromyopathy; neuropathy peripheral; neuropathy vitamin B ₆ deficiency; neurotoxicity; paresthesia; peripheral motor neuropathy; peripheral nerve lesion; peripheral nerve palsy; peripheral nervous system function test abnormal; peripheral sensorimotor neuropathy; peripheral sensory neuropathy; peroneal muscular atrophy; peroneal nerve palsy; phrenic nerve paralysis; polyneuropathy; polyneuropathy chronic; polyneuropathy idiopathic progressive; radiation neuropathy; sensorimotor disorder; sensory disturbance; sensory loss; skin burning sensation; temperature perception test decreased; Tinel sign; toxic neuropathy; or ulnar neuritis
Neutropenia	Febrile neutropenia; neutropenia; or neutrophil count decreased
Pulmonary embolism	Pulmonary artery thrombosis; pulmonary embolism; or pulmonary thrombosis
Radiation-induced interstitial lung disease	Pulmonary radiation injury; radiation alveolitis; radiation fibrosis - lung; or radiation pneumonitis
Renal cyst	Renal abscess; renal cyst; renal cyst excision; renal cyst hemorrhage; renal cyst infection; or renal cyst ruptured
Stomatitis	Cheilitis; glossitis; glossodynia; mouth ulceration; mucosal inflammation; oral pain; oropharyngeal discomfort; oropharyngeal pain; or stomatitis
Thrombocytopenia	Platelet count decreased; or thrombocytopenia
Upper respiratory infection	Laryngitis; nasopharyngitis; pharyngitis; rhinitis; or upper respiratory tract infection
Vision disorder	Chromatopsia; diplopia; halo vision; photophobia; photopsia; vision blurred; visual acuity reduced; visual brightness; visual field defect; visual impairment; or vitreous floaters

ALT, alanine aminotransferase; AST, aspartate aminotransferase; MedDRA, Medical Dictionary for Regulatory Activities.^{a)} There were differences between PROFILE 1007 and PROFILE 1014 in the conditions/symptoms included in some of the clustered terms.