

**Adult-Related Conditions that qualify for a waiver because they rarely or never occur in pediatrics\***

These conditions qualify for waiver because studies would be impossible or highly impractical.

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| actinic keratosis   | erectile dysfunction essential thrombocytosis  |
| acute bacterial exacerbations of chronic<br>bronchitis (a complication of chronic<br>obstructive pulmonary disease) | giant cell arteritis   |
| adjunctive treatment of major depressive<br>disorder  | gout   |
| age-related macular degeneration (AMD)  | heavy menstrual bleeding associated with uterine<br>fibroids   |
| Alzheimer's disease amyloidosis   | Huntington's chorea  |
| amyotrophic lateral sclerosis   | idiopathic pulmonary fibrosis  |
| androgenic alopecia   | infertility & reproductive technology  |
| axial spondyloarthropathies including ankylosing<br>spondylitis   | juvenile psoriatic arthritis (pJIA)  |
| atherosclerotic cardiovascular disease  | memory loss  |
| benign monoclonal gammopathy  | menopause and perimenopausal disorders   |
| benign prostatic hyperplasia  | mesothelioma   |
| cancer:   | microscopic polyangiitis   |
| basal cell and squamous cell skin cancer  | myelodysplasia   |
| bladder breast cervical colorectal  | myelofibrosis & myeloproliferative disorders   |
| cholangiocarcinoma  | opioid induced constipation in chronic, non-<br>cancer pain  |
| endometrial   | osteoarthritis   |
| esophageal  | overactive bladder   |
| fallopian tube  | Parkinson's disease  |
| follicular lymphoma   | paroxysmal nocturnal hemoglobinuria  |
| gastric   | plasma cells and antibody production disorders   |
| hairy cell leukemia   | polycythemia vera  |
| hepatocellular  | polymyalgia rheumatica (PMR)   |
| indolent non-Hodgkin lymphoma   | postmenopausal osteoporosis  |
| liposarcoma   | presbyopia   |
| lung (small & non-small cell)   | prevention of stroke and systemic embolic events<br>in atrial fibrillation   |
| multiple myeloma  | psoriatic arthritis  |
| oropharynx (squamous cell)  | reduction of thrombotic cardiovascular events in<br>patients with coronary artery disease                            |
| ovarian (non-germ cell) pancreatic  | replacement therapy in males for conditions<br>associated with a deficiency or absence of<br>endogenous testosterone |
| peritoneal  | retinal vein occlusions stress urinary incontinence  |
| prostate  | Sjogren's Syndrome   |
| renal cell uterine  | temporary improvement in the appearance of<br>glabellar, canthal, and/or forehead lines                              |
| chronic lymphocytic leukemia  | treatment of incompetent great saphenous veins<br>and varicosities   |
| chronic obstructive pulmonary disease (COPD)  | treatment of Hypoactive Sexual Desire Disorder<br>(HSDD) in postmenopausal women                                     |
| cryoglobulinemia  | type 2 diabetic mellitus with cardiovascular disease   |
| degenerative intervertebral disc disease  | type 2 diabetic nephropathy  |
| diabetic foot infections  | vascular dementia/vascular cognitive disorder/<br>impairment   |
| diabetic gastroparesis  |  |
| diabetic peripheral neuropathy/macular edema  |  |
| diabetic retinopathy  |  |
| digestive disorders (gallstones)  |  |
| dry eye syndrome (keratoconjunctivitis sicca)   |  |
| dupuytren's disease and manifestations  |  |