



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

**TERTIARY AND QUATERNARY LEVEL
ESSENTIAL MEDICINES RECOMMENDATIONS**

April 2016

TERTIARY AND QUATERNARY LEVEL ESSENTIAL MEDICINES RECOMMENDATIONS

| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
|--|---|--|--|
| A ALIMENTARY TRACT AND METABOLISM | | | |
| A04AA01/ A04AA02 | 5HT3 antagonists Ondansetron and Granisetron | Highly emetogenic chemotherapy. | Recommended |
| A05AA02 | Ursodeoxycholic acid | Primary biliary cirrhosis. | Not recommended |
| A07EC02 | Mesalazine | Ulcerative colitis – maintenance of remission. | Not recommended - May be used on a named-patient basis, on recommendation by PTC for patients with sulphonamide hypersensitivity. |
| A10BG03 | Pioglitazone | Type 2 diabetes mellitus. | Not recommended |
| A16AA03 | Glutamine | Glutamine as a component of enteral and parenteral nutrition in critically ill patients. | Not recommended |
| B BLOOD AND BLOOD FORMING ORGANS | | | |
| B01AC04 | Clopidogrel | Percutaneous coronary intervention (stenting). | Recommended Clopidogrel plus aspirin recommended for a minimum of: <ul style="list-style-type: none"> • 30 days in situations where a bare metal stent is inserted. • 90 days in situations where a sirolimus drug-eluting stent is inserted. • 180 days when a paclitaxel drug-eluting stent is inserted. Thereafter allow aspirin indefinitely. The evidence currently available to the Committee does not provide support for use beyond 6 months although there are recommendations endorsing longer term use in high risk patients. |
| B01AC04 | Clopidogrel | Ischaemic heart disease (non myocardial infarction). | Recommended for use only in patients intolerant to aspirin, i.e. allergy or bleeding episodes. |
| B01AC04 | Clopidogrel | Stroke. | Only recommended for long-term therapy where patient has confirmed aspirin intolerance. |
| B01AC04 | Clopidogrel | Transient ischaemic attack with/without atrial fibrillation. | Not recommended |

| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
|--|--|---|--|
| B01AD02 | Tissue plasminogen activator | For acute ischaemic stroke. | Recommended: with the following provisos: 1. Patients presenting within 3 hours of onset, and where specialised neuro-radiological services are available. |
| C CARDIAC THERAPY | | | |
| C02DC01 | Minoxidil | Severe hypertension not responding to other drugs. | Recommended |
| C09CA | Angiotensin receptor blockers (ARBs) | Add on therapy in cardiac failure on patients already on standard treatment including ACE-inhibitors, β -Blockers and spironolactone. | Not recommended |
| C09CA | Angiotensin receptor blockers (ARBs) | As add on therapy in proteinuric nephropathies in patients already using an ACE-inhibitor. | Not recommended Insufficient evidence to support its use. |
| D ANTIPRURITICS, INCLUDING ANTIHISTAMINES, ANAESTHETICS, ETC. | | | |
| D07AC | Potent topical corticosteroid – Group III e.g. <i>Betamethasone 0.05%-0.1%</i> <i>Fluticasone 0.05%</i> <i>Methylprednisolone aceponate 0.1%</i> <i>Mometasone 0.1%</i> | | Recommended |
| D07AD | Very potent topical corticosteroid – Group IV e.g. <i>Clobetasol 0.05%</i> | | Recommended Examples: Cream/ointment: • Clobetasol propionate 0.05%. Lowest price high potency corticosteroid to be used. |
| D10BA01 | Isotretinoin | Cystic nodular acne. | Not recommended |
| G GENITO URINARY SYSTEM AND SEX HORMONES | | | |
| G03HB01 | Cyproterone, ethinyl oestradiol | Hirsutism. | Recommended |
| G04BD10 | Urinary antispasmodics | Over active bladder (OAB) with symptoms of urinary urgency, frequency and/or urge incontinence. | Not recommended |
| | Darifenacin | | |
| G04CB01 | Finasteride | Benign prostatic hyperplasia. | Not recommended |

| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
|--|-------------------------------------|---|---|
| H SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS | | | |
| H01AA01 | Adrenocorticotrophic hormone (ACTH) | Infantile spasms. | Not recommended |
| H01AC01 | Somatropin (Growth Hormone) | Turner's syndrome. | Not recommended |
| H01AC01 | Somatropin (Growth Hormone) | Prader Willi syndrome. | Not recommended |
| H01AC01 | Somatropin (Growth Hormone) | Intrauterine growth failure. | Not recommended |
| H01AC01 | Somatropin (Growth Hormone) | Idiopathic short stature. | Not recommended |
| H01AC01 | Somatropin (Growth Hormone) | Chronic renal insufficiency. | Not recommended |
| H01AC01 | Somatropin (Growth Hormone) | Growth hormone deficiency. | Recommended Recommended for confirmed growth hormone deficiency for use by endocrinologists only. Rationale: <ul style="list-style-type: none"> The condition is a well defined deficiency state that can be managed and monitored. Number of patients requiring treatment is small. |
| H01BA05 | Ornipressin | Bleeding associated with bronchoscopy and renal biopsy. | Not recommended |
| H01CB02 | Octreotide (Short-acting) | Persistent neonatal hyperinsulinism and hypoglycaemia. | Recommended The condition is rare; usage is for short term; alternative agents are limited and the consequences of not having treatment available are serious. |
| H01CB | Somatostatin analogs | Neuro-endocrine tumours | Not recommended |
| | Octreotide and lanreotide | | |

| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
|---|---|--|--|
| J ANTI-INFECTIVES FOR SYSTEMIC USE | | | |
| J01XC01 | Fusidic acid | Treatment of staphylococcal infections, mainly involving bone and joints: <ul style="list-style-type: none"> • Methicillin-sensitive organisms, as alternative to cloxacillin or flucloxacillin. • Methicillin-sensitive organisms, in combination with cloxacillin or flucloxacillin. • Methicillin-resistant organisms, as an alternative to e.g. glycopeptides or oxazolidinones (linezolid), especially in cases where prolonged treatment is required. | Not recommended |
| J01XX08 | Linezolid | Resistant gram positive infections where vancomycin is contra-indicated. | Recommended |
| J02AB02 | Ketoconazole | Cushing's syndrome. | Recommended |
| J02AC02 | Itraconazole | Histoplasmosis. | Not recommended |
| J02AC03 | Voriconazole (VCZ) | Treatment of invasive Aspergillosis. | Not recommended |
| J05AB04 | Ribavirin | Viral haemorrhagic fever (VHF). | Recommended To be supplied on motivation from a central supply point. |
| J06BB16 | Palivizumab | Respiratory syncytial virus (RSV) infection. | Not recommended |
| L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS | | | |
| L01 | Chemotherapy Platinum coordination compounds, Taxanes, Doxorubicin, cyclophosphamide | Uterine Cancer/ Endometrial Cancer (Advanced stage and recurrent). | Not recommended |
| L01AA01 | Cyclophosphamide | Adjuvant breast cancer. | Recommended (Cyclophosphamide plus adriamycin (AC)). |
| L01AA01 | Cyclophosphamide | Adjuvant breast cancer. | Recommended (Cyclophosphamide plus methotrexate plus fluoro-uracil (CMF)). |
| L01AA01 | Methotrexate | Adjuvant breast cancer. | Recommended (Cyclophosphamide plus methotrexate plus fluoro-uracil (CMF)). |
| L01AA01 | Cyclophosphamide | Adjuvant breast cancer. | Recommended (Fluoro-uracil plus adriamycin plus cyclophosphamide (FAC)). |

| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
|---|--|---|---|
| L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS | | | |
| L01AX03 | Temozolomide | Glioblastoma multiforme. | Not recommended |
| L01BA04 | Pemetrexed | Lung mesothelioma. | Not recommended |
| L01BA04 | Pemetrexed | Non-small cell lung cancer. | Not recommended |
| L01BC06 | Capecitabine | Metastatic colorectal – first-line. | Recommended (as part of the XELOX regimen). |
| L01BC06 | Capecitabine | First-line therapy for advanced stomach/gastro-oesophageal junction cancer. | Recommended |
| L01BC52 | Fluoro-uracil | Adjuvant breast cancer. | Recommended (Cyclophosphamide plus methotrexate plus fluoro-uracil (CMF)). |
| L01BC52 | Fluoro-uracil | Adjuvant colorectal cancer. | Recommended (Fluoro-uracil plus adriamycin plus cyclophosphamide (FAC)). |
| L01BC52 | Fluoro-uracil | Adjuvant breast cancer. | Recommended (Fluorouracil plus adriamycin plus cyclophosphamide (FAC)). |
| L01CA04 | Vinorelbine | Adjuvant non-small cell lung cancer – completely resected. | Recommended |
| L01CD | Taxanes (Docetaxel and paclitaxel) | Adjuvant breast cancer. | Recommended Recommended for patients with high grade, node positive ER negative disease. |
| L01CD01 | Paclitaxel | Neoadjuvant/recurrent/metastatic head and neck cancer. | Not recommended |
| L01CD01 | Paclitaxel | First-line chemotherapy in advanced non-small cell lung cancer (NSCLC). | Recommended |
| L01CD | Taxanes | Metastatic breast cancer – first- and secondline. | Recommended |
| L01CD02 | Docetaxel | Squamous cell carcinoma of head and neck. | Recommended Recommended for patients with good performance status and adequate follow-up used in combination with cisplatin plus 5-fluoro-uracil. |
| L01CD02 | Docetaxel | Second-line therapy for advanced non-small cell lung cancer (NSCLC) in selected patients with good performance status (ECOG 0;1). | Recommended |
| L01DB01 | Adriamycin | Adjuvant breast cancer. | Recommended (Adriamycin plus cyclophosphamide (AC)). |

| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
|---|---|---|---|
| L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS | | | |
| L01DB01 | Adriamycin | Adjuvant breast cancer. | Recommended (Fluoro-uracil plus adriamycin plus cyclophosphamide (FAC)). |
| L01DB06 | Idarubicin | Acute Myeloid Leukemia. | Recommended |
| L01DB03 | Epirubicin | Advanced stage or metastatic oesophageal junction and gastric carcinoma. | Recommended |
| L01XA01 | Cisplatin | Adjuvant small cell lung cancer. | Recommended |
| L01XA01 | Cisplatin | Adjuvant lung cancer. | Recommended |
| L01XA02 | Carboplatin | Adjuvant lung cancer. | Recommended |
| L01XA02 | Etoposide | Adjuvant small cell lung cancer. | Recommended |
| L01XA03 | Oxaliplatin | Adjuvant colorectal. | Not recommended |
| L01XA03 | Oxaliplatin | First or second-line metastatic colorectal cancer. | Recommended |
| L01XC07 | Bevacizumab | Sub-retinal neovascular membranes and non-resolving macular odema. | Recommended (off label indication). |
| L01XE01 | Imatinib | Chronic phase of chronic myeloid leukemia. | Recommended |
| L01XE01 | Imatinib | Gastrointestinal Stromal Tumours (GIST) - adjuvant therapy. | Recommended |
| L01XE01 | Imatinib | Gastrointestinal Stromal Tumours (GIST) - metastatic therapy. | Recommended |
| L01XE08 | Nilotinib | Chronic Myeloid Leukemia in patients resistant or intolerant to imatinib. | Recommended |
| L01XC02 | Rituximab | CD20 positive B-cell non-Hodgkin's lymphoma – 1 st line. | Recommended for treatment in diffuse large B-cell non-Hodgkin's lymphoma (DLBCL) patients except those with International Prognostic Index (IPI) of 0. |
| L01XX19 | Irinotecan | Adjuvant colorectal. | Not recommended |
| L01XX19 | Irinotecan | First- or second-line metastatic colorectal cancer. | Recommended |
| L02AE03 | Gonadotrophin-releasing hormone (GnRH) analogue Goserelin and buserelin | Endometriosis. | Recommended for use in the following situations: <ul style="list-style-type: none"> • For endometriosis-associated infertility prior to in vitro fertilisation (IVF). For medical management in situations in which a trial of adequate analgesia or the use of combined oral contraceptives is unsuccessful. |

| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
|---|---|---|--|
| L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS | | | |
| L02AE03 | Gonadotrophin-releasing hormone (GnRH) analogue | Precocious puberty. | Recommended Choice of GnRH analogue will depend on best tender price. |
| L02AE03 | Gonadotrophin-releasing hormone (GnRH) analogue | As bridging therapy until orchiectomy. | Recommended Only recommended as bridging therapy - not long term management. |
| L02AE03 | Goserelin | Hormone receptor positive breast cancer in premenopausal women. | Not recommended |
| L02BA01 | Tamoxifen | Adjuvant breast cancer. | Recommended |
| L02BA01 | Tamoxifen | Metastatic breast cancer. | Recommended |
| L02BB01/ L02BB03 | Anti-androgens Flutamide/ Bicalutamide | Advanced prostate cancer. | Not recommended Orchiectomy preferred. |
| L01BC05 | Gemcitabine | Pancreatic cancer. | Not recommended |
| L01BC05 | Gemcitabine | Firstline chemotherapy in advanced non-small cell lung cancer (NSCLC) in patients intolerant to paclitaxel. | Recommended Recommended in patients intolerant to paclitaxel. |
| L02BG | Aromatase inhibitors (Anastrozole, letrozole, exemestane) | Adjuvant breast cancer. | Recommended for use in women with confirmed intolerance to tamoxifen, i.e. thrombo-embolic disease or endometrial hyperplasia (proven on ultrasound). Choice of aromatase inhibitor will depend on best tender price. |
| L02BG | Aromatase inhibitors | Metastatic breast cancer. | Recommended for use as second-line therapy after tamoxifen in advanced breast cancer in postmenopausal women who do not have visceral metastases. Choice of aromatase inhibitor will depend on best tender price. |
| L03AA02 | Filgrastim | Neutropenic sepsis. | Recommended under the following conditions: <ul style="list-style-type: none"> Patients must have had 3 days of appropriate antimicrobial therapy without resolution of infection. Filgrastim can be used up to a maximum of 5 days with a daily review of white cell count (WCC). Failure to respond must prompt further investigation of neutropenia. |
| L03AA02 | Filgrastim | ARV-induced neutropenia. | Not recommended This does not preclude the use of filgrastim in the management of febrile neutropenia (see above) in HIV infected patients. |
| L03AA02 | Filgrastim | Prophylactic use in children with high-risk acute lymphoblastic leukaemia (HR-ALL). | Not recommended |

| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
|---|------------------------------------|--|--|
| L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS | | | |
| L03AA10 | Filgrastim | Peripheral blood stem cell harvesting in autologous stem cell harvesting in haematological malignancies. | Recommended |
| L03AA02 | Filgrastim | Chemotherapy-induced febrile neutropenia. | Recommended for secondary prophylaxis in curable cancers requiring full dosing on-schedule, i.e. Hodgkins and germ cell tumours. Not recommended for primary prophylaxis as no overall survival benefit and limited mortality benefit has been shown. |
| L04AA10 | Sirolimus | Renal transplant. | Recommended for use only patients with biopsy-confirmed calcineurin inhibitor toxicity because of deteriorating kidney function (i.e. in patients at ongoing risk of acute rejection with no overt proteinuria and preserved GFR > 40mL/min) where mycophenolate mofetil is contra-indicated. |
| L04AA | Mycophenolate mofetil (MMF) | Lupus Nephritis. | Recommended for both the induction and maintenance phases of treatment of lupus nephritis. |
| L04AA | Mycophenolate mofetil (MMF) | Prevention of acute rejection post-renal transplantation. | Recommended for prevention of acute rejection post-renal transplantation. |
| L04AA13 | Leflunomide | As add-on therapy in Rheumatoid Arthritis. | Not recommended May be used on a named-patient basis, on recommendation by PTC for intolerance to standard therapy. |
| L04AA04 | Antithymocyte immunoglobulin (ATG) | Aplastic Anaemia. | Recommended |
| L04AB02 | Infliximab | Fistulising Crohn's Disease. | Not recommended |
| L04AB02 | Infliximab | Rheumatoid Arthritis. | Not recommended |
| L04AD01 | Ciclosporin | Organ transplantation. | Recommended |
| L04AD02 | Tacrolimus | Second-line agent for renal transplantation in patients intolerant to ciclosporin. | Not recommended |
| L04AX02 | Thalidomide | Multiple myeloma. | Not recommended |

| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
|---------------------------------|---|---|--|
| M MUSCULOSKELETAL SYSTEM | | | |
| M03BX01 | Baclofen | Spasticity. | Not recommended |
| M03AX01 | Botulinum toxin | Focal dystonias. | Recommended for use in carefully selected patients. Only to be administered by suitably experienced practitioners. |
| M03AX01 | Botulinum toxin | Spastic cerebral palsy. | Not recommended |
| M05BA | Bisphosphonates | Malignant bone disease in multiple myeloma. | Recommended |
| | Zoledronate Ibandronic acid | | |
| M05BA03 | Pamidronate | Hypercalcaemia of malignancy. | Recommended |
| M05BA04 | Alendronate | Osteogenesis imperfect. | Not recommended |
| M03BX01 | Baclofen | Spasticity. | Not recommended |
| M05BA04 | Alendronate | Corticosteroid induced osteoporosis. | Recommended for use only in patients fulfilling criteria similar to those for postmenopausal osteoporosis (i.e. patients who have a T-score of -2.5 plus established fracture). |
| M05BA04 | Alendronate | Paget's. | Not recommended |
| M05BA04 | Alendronate | Osteogenesis imperfect. | Not recommended |
| N NERVOUS SYSTEM | | | |
| N03AG04 | Vigabatrin | Refractory partial epilepsy. | Not recommended |
| N03AG04 | Vigabatrin | Infantile spasms. | Not recommended |
| N03AX11 | Topiramate | Initial therapy (epilepsy). | Not recommended |
| N03AX11 | Topiramate | Add-on therapy for resistant epilepsy. | Recommended |
| N03AX14 | Levetiracetam | Epilepsy. | Not recommended |
| N03AX14 | Levetiracetam | Add-on therapy for resistant epilepsy. | Not recommended |
| N04BC04/ N04BC05 G02CB01 | Dopamine agonist | Parkinson's disease. | Recommended for use as add-on therapy to levodopa. The choice of dopamine agonists and selegiline will depend on the lowest tender price. |
| | Ropinarole and pramipexole bromocriptine) | | |
| N05AH03 | Olanzapine, IM | Emergency management of psychotic conditions. | Not recommended |
| N05AH04 | Quetiapine | Bipolar depression | Not recommended |
| N05AX08 | Risperidone depot | Schizophrenia. | Not recommended |

| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
|-------------------------|-------------------------------------|--|--|
| N NERVOUS SYSTEM | | | |
| N05AL05 | Amisulpride | Psychosis. | Recommended for use as an appropriate alternative to existing agents in patients with negative symptoms failing first and second generation antipsychotics. |
| N05AX12 | Aripiprazole | Schizophrenia in children. | Recommended for use as a third-line agent in children with psychotic disorders who are intolerant to typical and atypical antipsychotic agents with: <ul style="list-style-type: none"> • Obesity, defined as BMI \geq 30 or age appropriate measures, or • Excessive weight gain, if associated with metabolic syndrome in adherent patients on other atypical antipsychotics, not responsive to other interventions (e.g. dietary management and/or physical exercise). Aripiprazole be initiated, in these cases, in consultation with or, where available, by a subspecialist (i.e. child and adolescent psychiatrist). |
| N05BA12 | Alprazolam | “As required” adjunctive medication in the treatment of panic disorder. | Recommended for panic disorder only. To be prescribed by a psychiatrist. |
| N05CF01/ N05CF02 | Benzodiazepine related drugs | Short term use for insomnia associated with a primary psychiatric condition. | Not recommended |
| | Zopiclone/ Zolpidem | | |
| N06AB10 | Escitalopram | Depressive and anxiety disorders. | Not recommended |
| N06AX12 | Bupropion | Major depressive disorder. | Recommended for use as a third-line treatment of major depressive disorder and anxiety associated with depression. To be prescribed by a psychiatrist only. The cheapest of bupropion or venlafaxine to be used. |
| N06AX16 | Venlafaxine | Major depressive disorder. | Recommended for use as a third-line treatment of major depressive disorder and anxiety associated with depression. To be prescribed by a psychiatrist only. The cheapest of bupropion or venlafaxine to be used. |
| N06DX01 | Memantine | Alzheimer’s Disease. | Not recommended |

| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
|-----------------------------|--------------------------------|--|---|
| R RESPIRATORY SYSTEM | | | |
| R03DC03 | Montelukast | Chronic management of severe uncontrolled asthma. | <p>Recommended for use in:</p> <ul style="list-style-type: none"> In adults (>12 years) with difficult to control asthma despite receiving high dose inhaled steroids and long-acting β_2 agonist, a trial of low dose sustained release theophylline should be tried before use of montelukast. If there is no response to low dose theophylline, a 2-week trial of montelukast may be used. In children between 6 and 12 years of age with severe uncontrolled asthma despite being on high dose corticosteroids and long acting β_2 agonist, a 2-week trial of montelukast could be considered. <p>In children less than 6 years with severe uncontrolled asthma on high dose inhaled corticosteroids, a 2-week trial of montelukast could be considered. If no benefit can be demonstrated after this period, montelukast should be discontinued.</p> |
| V VARIOUS | | | |
| ATC CODE | MEDICINE | INDICATION | RECOMMENDATION |
| V03AC03 | Deferasirox | Treatment of transfusional iron overload. | Not recommended |
| V03AF03 | Folinic acid, intravenous | Adjuvant colorectal cancer. | Recommended |
| V03AE | Lanthanum carbonate, Sevelamer | Hyperphosphataemia in patients with chronic renal failure. | Not recommended - May be used on a named-patient basis, on recommendation by the PTC. |

PTC: Pharmaceutical and Therapeutics Committee