Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) in the Long Term Care Setting

Part 3: Monitoring, Care Planning, and Counseling

Omnicare Pharmacy Services

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Overview - Part 3: Monitoring, Care Planning and Counseling

- Monitoring therapy and coordination of care
- Common opportunistic infections (OI) and treatments
- Counseling and pharmacy services

Monitoring Therapy: An Ongoing Process

- Continually monitor for side effects or adverse events related to HIV medications, or combinations of medications
- Work with your pharmacist

Table 18. Drugs That Should Not Be Used With Antiretroviral Agents (Last updated April 8, 2015; last reviewed April 8, 2015) (page 1 of 2)

This table only lists drugs that should not be coadministered at any dose, regardless of RTV or COBI enhancing. See Tables 19 and 20 for more detailed PK interaction data.

ARV Agents[a,b]	Cardiac Agents	Lipid-Lowering Agents	Antimycobacterial Agents	Antiepileptic Agents	Neurologic Agents	Herbs	HCV Agents[o]	Other Agents
ATV +/– RTV or COBI	Dronedarone Ranolazine	Lovastatin Simvastatin	Rifampin Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Irinotecan Salmeterol Sildenafil for PAH
DRV/c or DRV/r	Dronedarone Ranolazine	Lovastatin Simvastatin	Rifampin Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Dasabuvir Ombitasvir Paritaprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH
FPV +/– RTV	Dronedarone Flecainide Propafenone Ranolazine	Lovastatin Simvastatin	Rifampin Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Dasabuvir Ombitasvir Paritaprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH
LPV/r	Dronedarone Ranolazine	Lovastatin Simvastatin	Rifampin[p] Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Dasabuvir Ombitasvir Paritaprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH
SQV/r	Amiodarone Dofetilide Dronedarone Flecainide Lidocaine Propafenone Quinidine Ranolazine	Lovastatin Simvastatin	Rifampin[p] Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Trazodone Triazolam	Garlic supplements St. John's wort	Boceprevir Dasabuvir Ombitasvir Paritaprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH
TPV/r	Amiodarone Dronedarone Flecainide Propafenone Quinidine Ranolazine	Lovastatin Simvastatin	Rifampin Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Dasabuvir Ledipasvir Ombitasvir Paritaprevir Simeprevir Sofosbuvir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH

Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents
https://aidsinfo.nih.gov/guidelines
Table 18. Drugs That Should Not Be Used With Antiretroviral Agents

Monitoring

- Ongoing process of assessment
  - Labs
  - Physical
  - Psychological/psychosocial
- Residents are not only aging in place, they have multiple comorbid conditions that impact HIV and vice versa

Monitoring

- HIV brings unusual issues that require vigilance and understanding, these residents may be different from day to day
  - Example: neurocognitive dispersion - secondary to HIV and aging, resident displays an inconsistent, changing pattern of deficits in neurocognitive functioning, may indicate an incipient decline
  - Rule out: dementia progression, or HIV associated dementia (HAD; can typically be treated with the proper HIV medication)
- Due to this variability, an interdisciplinary approach and consistency in care is crucial to avoid missing critical symptoms of a change in condition

Wasting Syndrome: AIDS Defining Condition

Wasting Syndrome - HIV-associated wasting syndrome is considered an AIDS-defining condition

- Involuntary loss of more than **10%** of total body weight from baseline (or **≥ 5%** of usual body weight in 2-3-months), AND more than ***30 days*** of either diarrhea *or* weakness and fever
- Wasting refers to a loss of muscle mass, though part of the weight loss may also be due to loss of fat

https://www.aids.gov/hiv-aids-basics/
http://www.hivguidelines.org/clinical-guidelines/adults/general-nutrition-weight-loss-and-wasting-syndrome/

Wasting Syndrome: AIDS Defining Condition

Wasting Syndrome - HIV-associated wasting syndrome is considered an AIDS-defining condition

- While this is often a sign of late stage disease, wasting syndrome can be treated by:
  - Proper diet
  - Medications to stimulate appetite
  - Medications to control diarrhea
  - Hormonal therapy to build muscle

https://www.aids.gov/hiv-aids-basics/
http://www.hivguidelines.org/clinical-guidelines/adults/general-nutrition-weight-loss-and-wasting-syndrome/

Monitoring: Labs

A number of laboratory tests are important in HIV treatment, timing is important:

- Initial evaluation of HIV-infected patients upon entry into care
- During follow-up if antiretroviral therapy (ART) is not initiated
- Before and after initiation or modification of therapy
- Assess the virologic and immunologic efficacy of ART regularly
- Monitor for laboratory abnormalities that may be associated with antiretroviral (ARV) drugs

All monitoring should be individualized in the care plan and updated as needed

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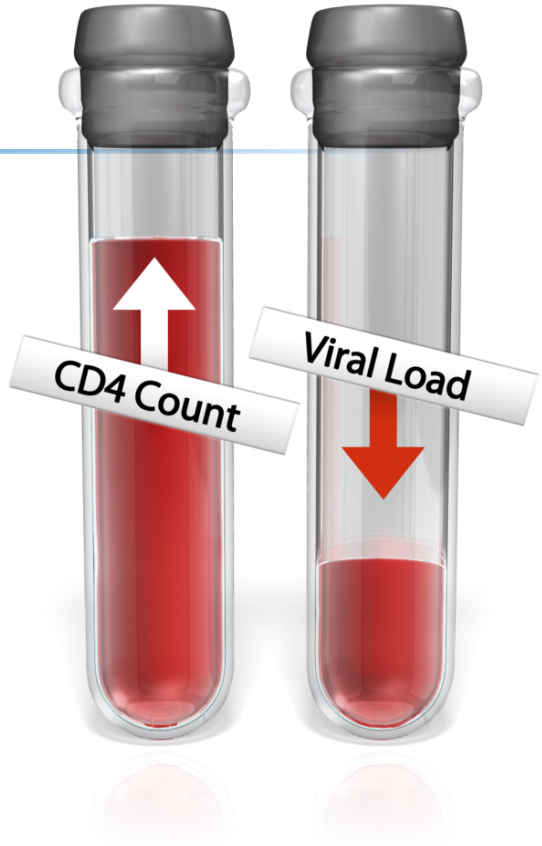
Monitoring: Labs

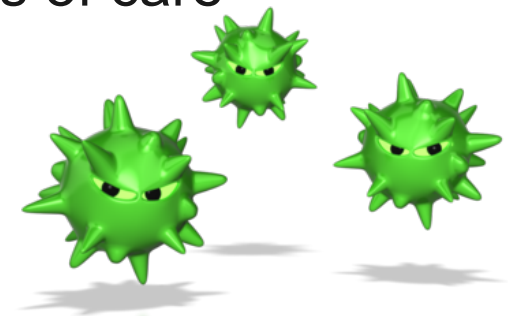
- Two surrogate markers are used routinely to assess immune function and level of HIV viremia:
  - CD4 T-cell count (CD4 count) – measures immune function and HIV disease progression
  - Plasma HIV RNA (viral load) – measures response to therapy, goal is viral suppression



Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Monitoring: Labs

- Resistance testing should be used to guide selection of the initial ARV regimen and/or when switching an ARV regimen
  - Resistance testing is often done with a specialist at a clinic
  - Facilities should try to get these results and place them in the chart for reference, to note in the care plan, and to assist if there are transitions of care



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Monitoring: Viral Load

Measure after initiation of ART or modification of therapy due to treatment failure

- **Plasma viral load should be measured:**
- Before initiation of ART ***and***
- Within 2 to 4 weeks but no later than 8 weeks after treatment initiation or modification
- Repeat viral load measurement at 4 to 8 week intervals until the level falls below the assay's limit of detection

In virologically suppressed patients in whom ART was modified due to drug toxicity or for regimen simplification

- Viral load measurement should be performed within 4 to 8 weeks after changing therapy
- The purpose of viral load monitoring at this point is to confirm the effectiveness of the new regimen

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Monitoring: Viral Load

In patients on a stable, suppressive ARV regimen

- Viral load should be repeated every 3 to 4 months, or as clinically indicated to confirm continuous viral suppression
- Doctors may extend the interval to 6 months for adherent patients whose viral load has been suppressed for ≥2 years and whose clinical and immunologic status is stable

In patients with suboptimal response

- The frequency of viral load monitoring will depend on clinical circumstances
- Patient adherence to prescribed medications, suboptimal drug exposure, or drug interactions, should be assessed
- Patients who do not achieve viral suppression require resistance testing to help select an alternative regimen

Goal viral load is HIV RNA less than 20 to 75 copies/mL

Note: the exact number depends on the lab that analyzes the sample

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Monitoring: CD4 Count

- **CD4 count is how we measure response to ART**
  - An adequate response is defined as an increase in CD4 count by 50 to150 cells/mm^3 in the 1st first year of ART
  - Subsequent increases average approximately 50 to 100 cells/ mm^3 per year until a steady state level is reached
  - Patients who initiate therapy with a low CD4 count or at an older age may have a blunted response, even when they have achieved virologic suppression

Goal CD4 count is ≥ 500 cells/mm^3

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Monitoring: CD4 Count

- **CD4 count frequency**
  - The frequency of CD4 count monitoring depends on clinical circumstances, but generally:
  - If untreated with ART, every 3 to 6 months to assess the urgency of ART initiation and the need for OI prophylaxis
  - 3 months after ART initiation, and for the first 2 years following ART initiation, at 3 to 6-month intervals, or as directed by a specialist
  - Residents taking ART whose CD4 count has consistently been between 300 and 500 cells/mm^3 $\geq$ 2 years, CD4 monitoring can occur on an annual basis, unless otherwise indicated

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Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents

Table 3. Laboratory Monitoring Schedule for HIV-Infected Patients Before and After Initiation of Antiretroviral Therapy

(page 1 of 2)

https://aidsinfo.nih.gov/guidelines

Laboratory Test	Timepoint/Frequency of Testing								
	Entry into Care	Follow Up Before Initiation of ART	ART Initiation or Modification[b]	Follow-Up 2 to 8 Weeks After ART Initiation or Modification	Every 3 to 6 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated
HIV Serology	√ If HIV diagnosis has not been confirmed								
CD4 Count	√	√ Every 3–6 months	√		√ During first 2 years of ART or if viremia develops while patient on ART or CD4 count <300 cells/mm^3		√ After 2 years on ART with consistently suppressed viral load: *CD4 Count 300–500 cells/mm^3:* • Every 12 months *CD4 Count >500 cells/mm^3:* • CD4 monitoring is optional	√	√
HIV Viral Load	√	Repeat testing is optional	√	√[c]	√[d]	√[d]		√	√
Resistance Testing	√		√[e]					√	√
HLA-B*5701 Testing			√ If considering ABC						
Tropism Testing			√ If considering a CCR5 antagonist					√ If considering a CCR5 antagonist or for failure of CCR5 antagonist-based regimen	√

Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents

Table 3. Laboratory Monitoring Schedule for HIV-Infected Patients Before and After Initiation of Antiretroviral Therapy

(page 2 of 2)

https://aidsinfo.nih.gov/guidelines

Laboratory Test	Timepoint/Frequency of Testing								
	Entry into Care	Follow Up Before Initiation of ART	ART Initiation or Modification[b]	Follow-Up 2 to 8 Weeks After ART Initiation or Modification	Every 3 to 6 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated
Hepatitis B Serology[f]	√		√ May repeat if HBsAg (-) and HBsAb (-) at baseline						√
Hepatitis C Serology, with Confirmation of Positive Results	√								√
Basic Chemistry[g,h]	√	√ Every 6–12 months	√	√	√				√
ALT, AST, T. bilirubin	√	√ Every 6–12 months	√	√	√				√
CBC with Differential	√	√ Every 3–6 months	√	√ If on ZDV	√				√
Fasting Lipid Profile	√	√ If normal, annually	√	√ Consider 4–8 weeks after starting new ART regimen that affects lipids		√ If abnormal at last measure-ment	√ If normal at last measurement		√
Fasting Glucose or Hemoglobin A1C	√	√ If normal, annually	√		√ If abnormal at last measure-ment		√ If normal at last measurement		√
Urinalysis[g]	√		√			√ If on TDF[i]	√		√
Pregnancy Test			√ In women with child-bearing potential						√

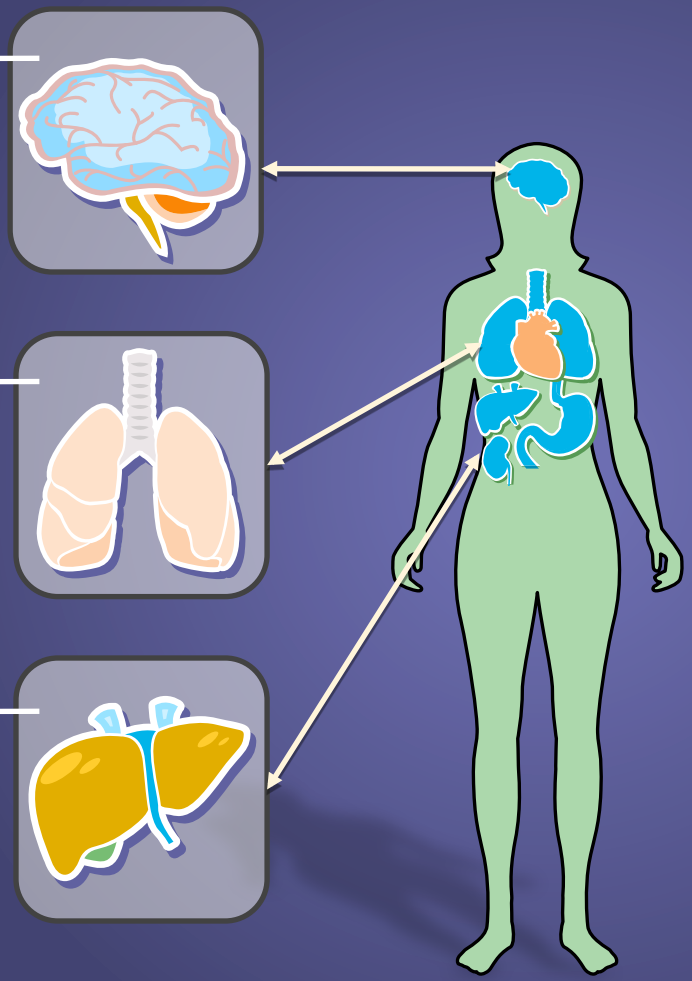
Opportunistic Infections (list not all inclusive)

BRAIN: Toxoplasmic Encephalitis

LUNGS: *Pneumocystis* pneumonia (PCP)

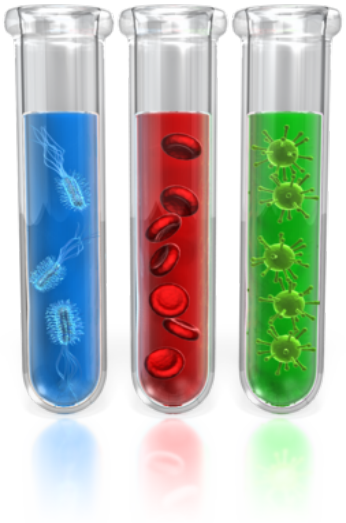
Tuberculosis

LIVER: Liver cancers often secondary to co-infection with hepatitis B and/or C



Multi-Organ Disease: *Mycobacterium avium* Complex (MAC)

Opportunistic Infections and Treatments



Rating of Recommendations:
A = Strong; B = Moderate; C = Optional
Rating of Evidence:
I = Data from randomized controlled trials;
II = Data from well-designed nonrandomized trials or observational
cohort studies with long-term clinical outcomes;
III = Expert opinion

Recommendations for Prevention and Treatment of *Pneumocystis* Pneumonia (PCP)

Preventing 1st Episode of PCP (Primary Prophylaxis)

Indications for Initiating Primary Prophylaxis:

- CD4 count <200 cells/mm³ **(AI)** *or*
- Oropharyngeal candidiasis **(AII)** *or*
- CD4% <14% **(BII)** *or*
- History of AIDS-defining illness **(BII)** *or*
- CD4 count >200 but <250 cells/mm³ and if CD4 cell count monitoring (e.g., every 3 months) is not possible **(BII)**.

Note—Patients who are receiving pyrimethamine/sulfadiazine for treatment or suppression of toxoplasmosis do not require additional prophylaxis for PCP **(AII)**.

Preferred Therapy:

- TMP-SMX, 1 DS PO daily[a] **(AI)** *or*
- TMP-SMX, 1 SS PO daily[a] **(AI)**.

Alternative Therapy:

- TMP-SMX 1 DS PO three times weeklya **(BI)** *or*
- Dapsone[b,c] 100 mg PO daily or 50 mg PO BID **(BI)** *or*
- Dapsone[b] 50 mg PO daily + (pyrimethamine 50 mg + leucovorin 25 mg) PO weekly **(BI)** *or*
- (Dapsone[b] 200 mg + pyrimethamine 75 mg + leucovorin 25 mg) PO weekly **(BI)** *or*
- Aerosolized pentamidine[c] 300 mg via Respigard II™ nebulizer every month **(BI)** *or*
- Atovaquone 1500 mg PO daily with food **(BI)** *or*
- (Atovaquone 1500 mg + pyrimethamine 25 mg + leucovorin 10 mg) PO daily with food **(CIII)**.

Indication for Discontinuing Primary Prophylaxis:

- CD4 count increased from <200 cells/mm³ to ≥200 cells/mm³ for at least 3 months in response to ART **(AI)**

Indication for Restarting Primary Prophylaxis:

- CD4 count <200 cells/mm³ **(AIII)**

Treating PCP

Note—Patients who develop PCP despite TMP-SMX prophylaxis usually can be treated effectively with standard doses of TMP-SMX **(BIII)**.

For Moderate to Severe PCP—Total Duration = 21 Days (AII):

Preferred Therapy:

- TMP-SMX: (TMP 15–20 mg and SMX 75–100 mg)/kg/day IV given q6h or q8h **(AI)**, may switch to PO after clinical improvement **(AI)**.

Alternative Therapy:

- Pentamidine 4 mg/kg IV once daily infused over at least 60 minutes **(AI)**; may reduce the dose to 3 mg/kg IV once daily because of toxicities **(BI)** *or*
- Primaquine[b] 30 mg (base) PO once daily + (Clindamycin [IV 600 q6h or 900 mg q8h] or [PO 450 mg q6h or 600 mg q8h]) **(AI)**.

**Adjunctive corticosteroid may be indicated in some moderate to severe cases (see indications and dosage recommendations below)

Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

NO OPPORTUNISTIC INFECTION TREATMENT IS EFFECTIVE WITHOUT ART

Opportunistic Infections and Treatments*

CD4 count: 500 cells/mm^3 to 200 cells/mm^3

- **Candidiasis (Thrush)**
  - Fungal infection that is commonly seen in patients with CD4 counts in this range
  - Treated with antifungal medications (e.g., fluconazole)

- List not all-inclusive for OI, or for treatments

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Opportunistic Infections and Treatments*

CD4 count: 200 cells/mm^3 to 100 cells/mm^3

- ***Pneumocystis* Pneumonia (PCP)**
  - Caused by *Pneumocystis jirovecii* (formerly *carinii*); frequently causes death in patients with HIV
  - Medications: trimethoprim-sulfamethoxazole (TMP-SMX) is the recommended prophylactic agent and treatment
  - Alternative medications: dapsone plus pyrimethamine plus leucovorin; aerosolized pentamidine administered with the Respirgard II nebulizer, or atovaquone
- **Progressive Multifocal Leukoencephalopathy (PML)**
  - PML is a severe neurological condition caused by the JC virus with no definitive treatment; however, it has been shown to be responsive to antiretroviral therapy.

- List not all-inclusive for OI, or for treatments

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Opportunistic Infections and Treatments*

CD4 count: 100 cells/mm^3 to 50 cells/mm^3

- **Toxoplasmosis**
  Caused by the parasite *Toxoplasma gondii,* causes encephalitis and neurological disease
  - Preventative Medications: trimethoprim-sulfamethoxazole (TMP-SMX)
  - Medications for treatment: pyrimethamine plus sulfadiazine plus leucovorin
- **Cryptosporidiosis**
  - Cryptosporidiosis is a severe chronic diarrheal disease caused by the protozoa *Cryptosporidium*.
  - Medications: Nitazoxanide, appropriate ART

- List not all-inclusive for OI, or for treatments

Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

Opportunistic Infections*

CD4 count: 50-100 cells/mm^3

- **Cytomegalovirus (CMV)**
  - Common virus, a majority of the population have had CMV by age 40
  - Retinitis is the most common clinical manifestation of CMV end-organ disease, regular eye exams are important
  - Medications: ART plus oral valganciclovir, intravenous (IV) ganciclovir, IV ganciclovir followed by oral valganciclovir, IV foscarnet, and IV cidofovir

- List not all-inclusive for OI, or for treatments

Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

Opportunistic Infections*

CD4 count: less than 50 cells/mm^3

- ***Mycobacterium avium* Complex (MAC)**
  - MAC is a type of bacteria that can be found in soil, water, and many places in the environment
  - Medications: azithromycin, clarithromycin, or rifabutin

- List not all-inclusive for OI, or for treatments

Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

CD4 Counts and Treatment* of Selected Opportunistic Infections

***Pneumocystis* pneumonia (PCP)**: Often treated with sulfamethoxazole/trimethoprim

Used to treat other conditions such as skin infections and urinary tract infections

Can be discontinued prematurely if the indication for use and intended duration of therapy are not noted on the order

Toxoplasmic encephalitis (TE):

Treated with numerous medications such as: clindamycin, sulfamethoxazole/trimethoprim, or pyrimethamine

Pyrimethamine causes bone marrow suppression, which is prevented by co-administration of leucovorin (folinic acid)

Detrimental side effects can occur if folic acid is given instead of folinic acid

- List not all-inclusive for OI, or for treatments

Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

CD4 Counts and Treatment* of Selected Opportunistic Infections

***Mycobacterium avium* complex (MAC)**: Often treated with azithromycin, longer/different dose than a Z-Pak

Clarithromycin and rifabutin are also used

Again, these meds can be prematurely discontinued if staff are unaware of the indication and intended duration of therapy

- List not all-inclusive for OI, or for treatments

Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

CD4 Counts and Treatment of Selected Opportunistic Infections (OI)

Often a CD4 count < 200 cells/mm^3 is a reason to start antibiotics to **prevent** an OI from occurring, particularly if a resident has had the infection in the past

Sometimes antibiotics or other treatments are initiated based irrespective of the CD4 count, but the intent is to treat or prevent an OI

These treatments are often medications frequently used for another condition in the LTC facility, and sometimes the resident has both an OI and another, more commonly seen infection

The duration of the antibiotic depends on many factors, but is typically prolonged in treatment or prophylaxis against an OI

Treatment for an OI can be accidentally discontinued too early, if the correct indication for use and expected duration of therapy is not noted in the chart

Note: if the electronic data entry system only allows for one diagnosis to be listed, we need a workaround to protect the resident

Counseling

- Never forget how valuable you are as a resource to your residents
- Residents with HIV need your clinical expertise, compassion, and communication skills on an ongoing basis
- Medication facts and information on disease progression are an integral part of the counseling process
- However, lifestyle modification reminders, such as avoiding alcohol, drugs, tobacco, and unsafe practices is just as important
- Pharmacists are here to help at the pharmacy, through medication therapy management (MTM) services, and through consulting services

References

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