YOUR NEW MEDICINES

General Overview

Your doctors have started you on many new medicines. These medicines are needed to make sure your transplant is successful. The medicines can be put into three different classes:

- **Anti-rejection** Help prevent your immune system from recognizing your new lung(s) as foreign
- **Anti-infective** Help protect you against certain infections
- Miscellaneous Medicines that treat the side effects of the anti-rejection medicines and other medical conditions



You MUST learn or know all of your medicines. You must carry a current list of your medications with you at ALL times.

Call your outpatient transplant coordinator two to three days in advance when you need a refill. Do not wait until your prescription runs out. Sometimes, you can time your refills with a return office visit. When you have an appointment, make a note of the medicines that you need to be renewed. Your doctor can refill them during your visit.

Your transplant medicines may have strong interactions with over-the-counter medicines.

- You may take Tylenol® (Acetaminophen) for minor aches and pains without contacting your outpatient coordinator.
- Do not take over-the-counter medicine (including "cold remedies") without contacting your outpatient coordinator first.

You Should Know

You should understand how they work, their side effects, and how to take as directed.

You Should Know

It is vital that you take ALL of your medicines.

- You should not take any medicine that contains ibuprofen or naproxen sodium (read the label carefully).
- Do not take any medicine prescribed by any other doctor (except your lung transplant doctor) without checking with your transplant coordinator first.

The following information will answer some of your questions about the medicines you will take. Not all of the medicines listed will apply to you. We have included them in case you need to learn about them in the future.

Anti-Rejection Medications

Tacrolimus (Prograf®) and Modified Cyclosporine (Neoral®, Gengraf®) are the primary medications to prevent rejection. You will be on one of these medicines after your transplant for life. Both of these medicines are adjusted by frequent blood levels. These blood levels

are called troughs and represent the lowest amount of tacrolimus/modified cyclosporine circulating in your body before you take your next dose. The blood must be drawn in the morning, about 11 to 12 hours after your last dose.

You Should Know

Do not take your morning dose until your blood is drawn!

If you miss a dose of Tacrolimus (Prograf®) or Modified Cyclosporine (Neoral®, Gengraf®), and it is within four

hours of your normally scheduled time, go ahead and take your dose. If it is past four hours, then contact your transplant coordinator or the physician right away. Don't decide what to do on your own. **Do not double the next dose!**

Medicine interactions: You must always be careful when taking new medicines. They can make your tacrolimus/cyclosporine level either go higher or lower. High tacrolimus/ cyclosporine levels could hurt your kidneys, cause other side effects, or raise your risk of getting an infection. Low tacrolimus/cyclosporine levels could increase your risk of rejection.

Besides medicines, certain foods can affect tacrolimus/cyclosporine levels, such as grapefruit, papaya, pomegranate, pomelo, starfruit and seville oranges. Never eat or drink these while taking tacrolimus/cyclosporine. They can increase the amount of these medicines in your body.

Tacrolimus (ta-KROE-li-mus) — Brand Name: Prograf® or Envarsus XR®

Possible Side Effects:

- Increased chance for infections
- Kidney problems
- Tremors
- Nausea/vomiting, diarrhea
- Headache
- Confusion
- Hard time sleeping
- High blood pressure
- High potassium levels and low magnesium levels (this can affect your heart)
- Diabetes-blood sugar problems
- Hair loss

Dosing strengths:

Tacrolimus Immediate Release (Prograf®, generic)

Frequency: Twice a day, 12 hours apart. Take consistently in relation to meals

Strengths: 0.5 mg capsule, 1 mg capsule, 5 mg capsule

Tacrolimus Extended Release (Envarus XR®)

Frequency: Once a day. Take consistently in relation to meals

Strengths: 0.75 mg tablet, 1 mg tablet, 4 mg tablet

Modified Cyclosporine (Sye-kloe-spor-een) — Brand Names: Neoral®, Gengraf®

Possible Side Effects:

- Increased chance for infections
- Kidney dysfunction
- Tremors
- Nausea/vomiting, diarrhea
- Headache
- High blood pressure
- High potassium levels
- Increased hair growth or hair in unusual places
- Gum hyperplasia (when the tissue around your teeth grows more than it should and can swell and bleed)
- Gout-painful joint

Dosing strengths: 25mg capsule

> 100mg capsule 100mg/ml solution

How Often: every 12 hours

Note: One brand name of cyclosporine may be absorbed differently in your body than another brand name. Only take the brand prescribed by your doctor or transplant coordinator.

Azathioprine (Imuran), Mycophenolate Mofetil (Cellcept), Mycophenolate Acid (Myfortic)

One of these medications will be your second anti-rejection medication. They are used together with the tacrolimus/modified cyclosporine. These medicines decrease white blood cells, and they are not monitored by blood levels.

Azathioprine (ay-za-THYE-oh-preen) — Brand Name: Imuran®

Possible Side Effects:

- Increased chance for infections
- Stomach upset and vomiting
- Diarrhea
- Blood test abnormalities
- Skin cancer
- Liver or pancreas abnormalities

Dosing Strength: 50mg tablet

How Often: One time a day

Mycophenolate mofetil (mye-koe-FEN-oh-late) — Brand Name: Cellcept® Mycophenolate sodium (mye-koe-FEN-oh-late) — Brand Name: Myfortic®

Possible Side Effects:

- Increased chance for infections
- Diarrhea, abdominal cramping
- Nausea, bloating
- Decrease white blood cell count

Cellcept®: 250 mg capsules, 500 mg tablets, 200 mg/ml suspension

Myfortic®: 180 mg tablets, 360 mg tablets

**Do NOT break tablets or open the capsules.

How Often: Two times a day (every 12 hours)

Mycophenolate in Pregnancy

Mycophenolate mofetil and mycophenolate sodium have been associated with miscarriage and birth defects. The Food and Drug Administration (FDA) requires the manufacturers of mycophenolate products to have a Risk and Evaluation Mitigation Strategy (REMs) to educate patients about the potential risks and the management of these risks.

Mycophenolate mofetil and mycophenolate sodium are used in combination with tacrolimus and cyclosporine. These medications can cause serious harm to a baby if taken while **pregnant.** Women of child bearing age should have a negative pregnancy test before starting this medication. Unless abstinence is the chosen method of birth control, effective medical or barrier contraception must be started before mycophenolate is initiated and continued during therapy and for six weeks after medication discontinuation. See pages 16 and 17 for more information on pregnancy and contraception methods. If you have any questions regarding these medications or pregnancy, please discuss this with your nurse or physician.

Sirolimus (Rapamune®), Everolimus (Zortress®)

Sirolimus and Everolimus are other anti-rejection medications that may be used together with tacrolimus, cyclosporine, mycophenolate or azathioprine, or by itself. However, they are not used within three months of lung transplant because of an increased risk of an opening forming at the place where the lungs are connected to your airway (bronchus).

Sirolimus and Everolimus are adjusted by frequent blood levels like tacrolimus/modified cyclosporine. These blood levels are called troughs and represent the lowest amount of sirolimus/everolimus circulating in your body before you take your next dose. The blood must be drawn in the morning, approximately 23 to 24 hours after your last sirolimus dose, and 11 to 12 hours after your last everolimus dose. Do not take sirolimus or everolimus until your blood is drawn!

Sirolimus (sir-OH-li-mus) — Brand Name: Rapamune®

Possible Side Effects:

- Increased chance for infections
- Low white blood cell count
- Low red blood cell count
- Low platelet count
- High cholesterol and triglyceride
- Delayed wound healing

Dose Strengths: 0.5 mg tablet

> 1mg tablet 2mg tablet

1mg/ml solution

How Often: One time a day

Everolimus (e-ver-OH-li-mus) — Brand Name: Zortress®

Possible Side Effects:

- Increased chance for infections
- Low white blood cell count
- Low red blood cell count
- High cholesterol and triglyceride
- Stomach upset and vomiting
- Diarrhea

Dose Strengths: 0.25 mg tablet

> 0.5 mg tablet 0.75 mg tablet

How Often: Every 12 hours

Prednisone (Deltasone)

Prednisone is the last anti-rejection medication you will take. At first it will be given as an intravenous (IV) form, methylprednisolone, right after surgery. Once you are able to swallow pills, the prednisone will be changed to oral pills. The dose will be adjusted slowly over time until it reaches a certain level. Once the level is chosen, you should maintain this dose until you are told by your doctor or transplant coordinator to change it. The IV form is also used to treat rejection episodes.

Possible Side Effects:

- Increased chance for infections
- Salt and fluid retention (swelling)
- Muscle weakness and loss of muscle mass
- Loss of calcium, leading to loss of bone density and a higher chance of bone fractures and osteoporosis
- Stomach ulcers
- Difficulty healing wounds, cuts and sores
- Changing body features: full cheeks, redistribution of body fat away from arms and legs and toward your stomach
- Increased appetite
- Menstrual irregularities
- Cataracts
- Elevation of blood glucose (you may require insulin)
- Dramatic changes in your emotions
- Insomnia
- Acne
- Change in hair condition. Permanent hair dyes, tints, wave lotions, and bleach may cause your hair to become brittle and break.
- High cholesterol

Dosing Strengths: 1mg tablets

> 2.5mg tablets 5mg tablets 20mg tablets 50mg tablets

How Often: One to two times a day

You Should Know

No blood levels are necessary to monitor the effectiveness of prednisone.

Anti-Infection Medications

After your transplant, you are at higher risk of becoming infected by bacteria, fungus or viruses found in your surroundings. Your doctor will prescribe several medications to help protect you. Over time, your doctor may decide to stop some of the medications described in this section.

Preventing Cytomegalovirus (CMV)

CMV is a common virus. You may have already been exposed to it. CMV is transmitted by body fluids such as blood, saliva, and breast milk. CMV may cause serious infections. The infections can lead to pneumonia, diarrhea, fever, weight loss, seizures, blindness, and encephalitis (infection of the brain). As a result, your doctor will prescribe Valganciclovir (Valcyte) pills or Ganciclovir (Cytovene) IV to help protect you from CMV infection. In addition, you may also need to receive Cytomegalovirus Immune Globulin (Cytogam) to protect you against developing CMV.

Valganciclovir (val gan SYE kloh veer) — Brand Name: Valcyte™

Possible Side Effects:

- Nausea, vomiting, diarrhea, abdominal cramping
- Headache
- Insomnia
- Anemia (low red blood cell count)
- Low white blood cell count
- Bruising, bleeding
- Fever/chills

Dosing Strengths: 450mg tablet

50mg/ml suspension

** Be careful to throw away any tablet that is broken or crushed.

How Often: One to two times a day with food

You Should Know

Take your Valcyte with food.

Cytomegalovirus Immune Globulin — Brand Name: Cytogam®

Possible Side Effects:

- Flushing, sweating
- Muscle cramps, back pain
- Stomach upset and vomiting
- Wheezing
- Chills, fever

You Should Know

- Given through an IV infusion in the hospital or clinic
- Total of six doses within first six months of transplant
- Can be given to treat an active infection

How Often: As directed by transplant team. Your transplant coordinator will arrange

IV infusions of this medication based on your individual case.

Preventing Herpes Simplex Virus (HSV)

You are protected against HSV (shingles) while on the above medication (Valcyte) for CMV prevention. If you have not been exposed to CMV or have finished your CMV prevention course, then you will be placed on Acyclovir.

Acyclovir (ay-sye-kloe-veer) — Brand Name: Zovirax®

Possible Side Effects:

- Nausea
- Vomiting
- Kidney dysfunction
- Visual changes
- Irritability, anxiety, confusion
- Low blood counts

Dosing Strengths: 200mg capsule

> 400mg tablet 800mg tablet

How Often: One to two times a day

Preventing Pneumocystis Jiroveci Pneumonia (PJP)

PJP can often lead to pneumonia. Because of this, your doctor will start you on a medicine called Bactrim. If you are allergic to sulfa-based medicines or to Bactrim, your doctor may prescribe either dapsone, atovaquone or pentamidine.

Sulfamethoxazole/trimethoprim (sul-Fa-meth-o-xa-zole or tri-meth-O-prim) — Brand Name: Bactrim™

Possible Side Effects:

- Itching
- Skin Rash
- Aching of joints and muscles
- Bleeding or bruising
- Sensitivity to sun

Dosing Strengths: 400mg/80mg (single strength tablet)

800mg/160mg (double strength tablet)

How Often: One time a day on Mondays, Wednesdays, and Fridays with food

Dapsone (DAP sone) — Brand Name: Avlosulfon®

Possible Side Effects:

- Rash
- Nausea/Vomiting
- Blood count abnormalities

Dosing Strength: 100mg tablet

How Often: One time a day on Mondays, Wednesdays and Fridays

Pentamidine (pen TAM i deen) — Brand Name: NebuPent™

Possible Side Effects:

- Bronchospasm
- Cough
- Irritation of the airway

Dosing Strength: 300mg inhalation

How Often: Once a month

Atovaquone (a TOE va kwone) — Brand Name: Mepron

Possible Side Effects:

- Headache
- Diarrhea
- Nausea

Dosing Strength: 1500 mg suspension

How Often: Once daily

Preventing Aspergillus

Aspergillus is a fungus found in our environment, and it is not dangerous for those with a normal immune system. Aspergillus most often infects the lung in patients who receive a transplant. You will be placed on an oral medication to prevent aspergillus post-transplant.

Oral Medications

Posaconazole (poe sa KON a zole) — Brand Name: Noxafil®

Possible Side Effects:

- Diarrhea
- Nausea/vomiting
- Visual changes
- Headache
- Elevated liver enzymes

Dosing strengths: 100mg tablet

How Often: One time a day with food

Other Medications

Sometimes there are side effects from one or more of the medicines you may take. So, you may be given another medicine to treat those side effects. If you are taking medicine for a medical condition you already have, this dose may be changed by your transplant doctor. Your transplant team will tell you when it is ok to continue taking the medicine.

This is a list of medicine that you may need to take:

Gastric Acid-Reducing Medicines: These medications protect the stomach lining from irritation or treat heartburn. Many of these medications can affect the absorption of some of your oral medicines. Examples of these medications include famotidine (Pepcid®), omeprazole (Prilosec[®]), esomeprazole (Nexium[®]), pantoprazole (Protonix[®]), and lansoprazole (Prevacid[®]).

Insulin: Tacrolimus and prednisone can cause your blood sugars to increase. Insulin and oral medications, such as glyburide or repaglinide, may be used to lower the blood sugars. High blood sugar may be a short-term or long-term problem. Long-term management of diabetes should be managed through your primary care doctor.

While on insulin, it is important to closely monitor blood sugars with a glucometer (measures blood sugars) at home. You will be taught how to use the glucometer and how to record your glucose levels.

Calcium: Some of the medications you are taking cause calcium loss. This can weaken your bones and put you at risk for developing osteoporosis. It is recommended for you to take a calcium supplement, such as calcium carbonate (Tums) or calcium citrate with vitamin D (Citracal with D), for prevention. Calcium is generally taken three times a day with meals. Vitamin D helps your body to better absorb the calcium.

Osteoporosis Prevention Medicines: Along with calcium, other medications can help protect you from getting osteoporosis. These drugs are taken once a week and must be taken first thing in the morning with a full glass of water. After you take the pill you can't lie down, take other medicines, eat or drink anything besides water (especially calcium) for at least 30 minutes. Some people have pain or trouble swallowing with this medicine. Examples of these medicines are alendronate (Fosamax®) and risedronate (Actonel®).

Magnesium: Some of your medicines cause magnesium loss. This can put you at risk for having irregular heart rhythms. Magnesium oxide will be prescribed to you right after your transplant to increase your magnesium. Some people may have diarrhea and gastrointestinal upset with this medicine.

High Blood Pressure Medicines: High blood pressure may be a result of the surgery and the anti-rejection medications. The high blood pressure may be a short-term or long-term problem.

Cholesterol Lowering Medicines: These drugs are also called "statins" and are used to lower your cholesterol. These drugs work best to prevent your body from making cholesterol when taken at night because this is when your body makes cholesterol. Some people get muscle aches or liver irritation with these drugs which your doctor will monitor. If you experience muscle aches or pains please let your transplant nurse and doctor know. Examples of these medicines include atorvastatin (Lipitor®) and simvastatin (Zocor®).

Approved Over-the-Counter (OTC) Medications

Below is a list of common symptoms and recommended over the counter treatment for symptom relief. Check with your transplant coordinator before taking any other medicines that are not listed below.

Constipation: Colace, Senekot, Benefiber, Fiber-con and Metamucil are medicines you may take. Eating a diet high in fiber (bran, fresh fruits and vegetables) and drinking more water will help with your constipation. Talk with your transplant coordinator if constipation remains a problem.

Diarrhea: Imodium and Kaopectate are acceptable medicines you may take. Drink more water and other fluids to prevent dehydration until your diarrhea goes away. Notify your transplant coordinator if your diarrhea lasts for more than two days.

Headache, muscle aches, other aches and pains: Tylenol (Acetaminophen) is an acceptable medicine to take. If your headache doesn't go away or you have a fever with your headache, call your transplant coordinator.

Over-the-Counter Medicines YOU SHOULD NOT TAKE!

These medicines will interact with your immune suppression medicine and may harm your kidneys. **DO NOT TAKE:**

- Ibuprofen
- Motrin-IB
- Advil
- Menadol
- Midol
- Genpril
- Ketoprofen
- Naproxen
- Aleve

You Should Know

We recommend that all transplant recipients avoid these products.

Allergy and cold medications: Do not take any cold medicines without the approval of your transplant coordinator.

Herbal Supplements

We recommend that you **DO NOT USE HERBAL SUPPLEMENTS**. There are many herbal supplements available to the public - often promoted as cures for many illnesses.

Herbal supplements are not regulated by the Federal Drug Administration (FDA) which means there are no standards for the ingredients used in each bottle of herbal supplements.

There can be a wide variation in the contents from one bottle to another – even with the same brand. Some supplements are harmless, but others can be a serious health risk. This is especially true of St. John's Wort, which causes many drug interactions. **ALL TRANSPLANT PATIENTS SHOULD NOT TAKE ST. JOHN'S WORT.**

Pregnancy After Solid Organ Transplantation

Pregnancy after solid organ transplantation consists of many uncertainties including the risks that pregnancy presents to your new organ, your personal health, and the health of your fetus (immediate and long term). Although successful pregnancies have occurred after transplantation, there are higher rates of fetal complications when compared to non-transplant patients including pre-term delivery, low birth weight, and toxemia (preeclampsia). In addition, pregnancy is associated with a higher frequency of rejection of the transplanted organ. Therefore, all pregnancies in transplant patients are considered to be high-risk so you must be managed by both your transplant physician and a high-risk obstetrician during pregnancy.

Exposure of infants to immunosuppressive medications may cause fetal harm. For example, the use of mycophenolate during pregnancy has been associated with miscarriage and birth defects. However, discontinuing these medications can result in rejection or loss of the transplanted organ. You should not discontinue any immunosuppressive medications without consulting with your transplant physician.

Some of the commonly used contraceptive methods may be less effective in combination with immunosuppressive medications or have an increased risk of infectious complications in transplant patients. Therefore, female transplant recipients must use the recommended individual or combinations of effective contraception methods during the entire treatment with mycophenolate and for six weeks after stopping mycophenolate.

ACCEPTABLE CONTRACEPTION METHODS — Choose One Option

Option 1

Methods to Use Alone

- Intrauterine devices (IUDs)
- Tubular sterilization
- Patient's partner had a vasectomy

Option 2

Choose One Hormone Method AND One Barrier Method

Hormone Methods (choose 1)

Estrogen and Progesterone

- Oral contraceptive pills
- Transdermal patch
- Vaginal ring

Progesterone only

- Injection
- Implant

AND

Barrier Methods (choose 1)

- Diaphragm with spermicide
- Cervical cap with spermicide
- Contraceptive sponge
- Male condom
- Female condom

Option 3

Choose One Barrier Method from EACH column (must chose **TWO** methods)

Barrier Methods (choose 1)

- Diaphragm with spermicide
- Cervical cap with spermicide
- Contraceptive sponge

AND

Barrier Methods (choose 1)

- Male condom
- Female condom