Pharmaceutical Failure Mode and Effects Analysis
Maraviroc (Selzentry)

· Step 1:

Describe how the intended product will be procured and used, from acquisition through administration.

Who will prescribe the drug and for what type of patient?
An Infectious Diseases Faculty or Fellow will prescribe this medication for patients with HIV who have previous treatment experience.

Where will the drug be stored?
It will be stored in the Inpatient Pharmacy at room temperature.

Who will prepare and dispense it?
Prescriptions will be prepared by pharmacy technicians and dispensed by pharmacists.

How will it be administered?
Maraviroc is administered orally twice a day.

· Step 2:

Identify potential failure modes (how and where systems and processes may fail) while considering how the product will be used.

Could the drug be mistaken for another similarly packaged product?
Both strengths of Selzentry (150 mg and 300 mg) are available in Pfizer bottles containing 60 tablets per bottle. The color of the bottle is unknown at this time.

Does the label clearly express the strength or concentration?
A description of the bottle label is unknown at this time.

Does the name sound or look like another drug on the formulary?
There is no other agent on formulary that sounds or looks like maraviroc.

Are dosing parameters complex?
The dosing regimen is simple (150 mg twice daily, 300 mg orally twice daily, or 600 mg twice daily) but is dependent on concomitant medications.

Recommended dosing is as follows:

<table>
<thead>
<tr>
<th>Concomitant Medications</th>
<th>Maraviroc Dose</th>
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</thead>
<tbody>
<tr>
<td>CYP3A inhibitors (with or without a CYP3A inducer) including:</td>
<td>150 mg twice daily</td>
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<tr>
<td>• protease inhibitors (except tipranavir/ritonavir delavirdine)</td>
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</tbody>
</table>
- ketoconazole, itraconazole, clarithromycin
- other strong CYP3A inhibitors (e.g., nefazadone, telithromycin)

| Other concomitant medications, including teparinavir/ritonavir, nevirapine, all NRTIs and enfuvirtide | 300 mg twice daily |
| CYP3A inducers (without a strong CYP3A inhibitor) including: | 600 mg twice daily |
| - efavirenz | |
| - rifampin | |
| - carbamazepine, phenobarbital, and phenytoin | |

Is the administration process error prone?
No

· **Step 3:**

Once failure modes have been identified, determine the likelihood of making a mistake and the potential consequences of an error.

What would happen to the patient if the drug were given in the wrong dose, at the wrong time, to the wrong patient, by the wrong route, at the wrong rate?
Doses higher than the recommended dose have resulted in symptomatic postural hypotension at greater frequency than placebo. A case of possible maraviroc-induced hepatotoxicity was reported in a study of healthy volunteers.

· **Step 4:**

Identify any preexisting processes in place that could help detect the error before it reaches the patient, and evaluate their effectiveness based upon knowledge of human factors.

There is a double check between the physician and the pharmacy and again between the pharmacy and nursing.

· **Step 5:**

If failure modes could cause errors with significant consequences, what actions could be taken to prevent the error, detect it before it reaches the patient, or minimize its consequences? (A few examples include: using an alternative product; preparing the drug in the pharmacy; standardizing drug concentrations, order communication and dosing methods; using auxiliary warning labels or computer alerts; and requiring entry of specific data into computer systems before processing orders).

The multiple double-checks between disciplines should be effective in catching potential errors.
Administration Information:

What are the most common side effects that Nursing should be aware of to ensure proper monitoring?
Cough, fever, upper respiratory infections, and rash.

Is there any associated laboratory monitoring that Nursing should be aware of to ensure proper patient care?
Liver function tests.