**Pharmacy and Therapeutics Committee**

**Generic Name (Brand Name) Monograph**

**AHFS Therapeutic Class:** [find in STAT!ref, from online clinical library]

**Manufacturer:**

**Operational Summary**

1. **Description/Mechanism**
   1. (availability considerations, if applicable: drop ship/next day delivery)
2. **FDA Labeled Indications**
3. **Dosing and Route of Administration**
   1. (pre-medications, if applicable)
4. **Preparation and Administration**
   1. (if applicable: vial size, diluent volume, pump bag or use pre-filled bag, add drug directly or remove volume first, pharmacy or nursing to prime line, what line, prime with diluent or active drug, protect from light and PVC requirements, duration of infusion, flushing instructions)
5. **Who may administer**
   1. (Ex: all RNs, or ICU RNs only, or MD only)
6. **Storage and stability** – should match IV room materials/product packaging
7. **Monitoring considerations** –
   1. Monitoring –
   2. Adverse reactions –
8. **Warnings and Precautions** –
   1. Hazardous risk category (if applicable)
   2. Contraindications –
   3. Warnings and Precautions –
   4. Drug interactions –
   5. Special Populations –
      1. Pregnancy –
      2. Breast feeding –
      3. (others, like pediatrics, if applicable)

**Executive Summary**

**Background and indication(s):**

**Efficacy:**

[Include a brief description of the trials (i.e. randomized, placebo-controlled, etc) and a brief description of patients (# of patients, general age, % woman/men). The next sentence should explicitly state ‘the primary outcome of xxxxx was seen in xx% of shingrix patients versus xx% of other group (p=x.xx).]

**Safety:**

[Common (>5%) adverse reactions were xx, xx, xx and xx. Adverse effects that lead to medication discontinuation included xx (xx%). State if the medication has a REMS program and why.]

**Pharmacoeconomics:**

**Summary:**

[One sentence about what the medication is and who it is used for. One sentence about the patients the medication has shown efficacy. One sentence about who is requesting and who (at UCSD) is planning to use. One sentence, without biased statements, about comparative efficacy to other treatments (if they exist) or efficacy in specific patient population. One sentence about cost to the organization.]

**The Bottom Line:**

|  |  |
| --- | --- |
| **Pro’s** | **Con’s** |
|  |  |
|  |  |
|  |  |

1. **Introduction:** [Brief discussion of the disease state and where this medication fits into the overall treatment scheme]
2. **FDA Approved Indication(s):** [include date of approval]
3. **Non-FDA Approved (Off-Label) Uses:** [per CMS-approved compendia, Clinical Pharmacology, Drugdex, NCCN, AHFS]
4. **Pharmacology/Pharmacokinetics:**
   1. **Pharmacology:**
   2. **Pharmacokinetics:** [Please provide a brief summary, in sentence form, of the pharmacokinetic data related to the medication. Please specify if the data was collected in humans or non-human subjects.]

**Table 1: Pharmacokinetics**

|  |  |
| --- | --- |
| *Half-life (active metabolite)* |  |
| *Bioavailability (Oral)* |  |
| *Cmax* |  |
| *Tmax* |  |
| *Food Effects* |  |
| *Protein Binding (Albumin)* |  |
| *Volume of distribution (Vd)* |  |
| *Excretion* |  |

1. **Dosage and administration:** [make sure to include additional information for IV products: standard concentration, preferred vehicle for mixing]
   1. **Renal dosing:**
   2. **Hepatic dosing:**
   3. **Other dosing (if applicable) considerations:**
2. **Clinical Efficacy:** [summarize key findings from the highest level of evidence available and include an evidence table in the appendix]
3. **Guideline Recommendations:** [provide current guideline recommendations for use of the medication and it’s place in therapy]
4. **Treatment/formulary Options:** [include all other comparator drugs available on formulary]
5. **Safety Considerations:** 
   1. **REMS:** [if yes, indicate medication guide, inpatient and/or outpatient prescribing requirements, registry requirements, etc.]
   2. **Boxed Warnings:**
   3. **Precautions/Contraindications:**
   4. **Sentinel Event Advisory:**
   5. **Adverse Effects:** [provide the most common and most serious adverse effects from package insert and/or clinical trials in a list or table format]

**Table 2 (example): Adverse Events Reported by >2% of Patients in Clinical Trials**

|  |  |  |  |
| --- | --- | --- | --- |
| **Event (examples)** | **Trial 1** | **Trial 2** | **Trial 3** |
| ***Dose 1*  (N=633)** | **Dose 2 (N=410)** | **Dose 3 (N=194)** |
| *Headache* | 60 (9%) | 34 (8%) | 32 (16%) |
| *Constipation* |  |  |  |
| *Diarrhea* |  |  |  |
| *Dizziness* |  |  |  |
| *Fatigue* |  |  |  |
| *Abdominal Pain* |  |  |  |
| *Insomnia* |  |  |  |

* 1. **Drug Interactions:**
  2. **Potential For Error:** [include any alerts from ISMP or FDA MedWatch]
     1. High alert medication: [if yes, explain reason behind high alert]
     2. Look alike/sound alike: [if yes, include what medication(s) it can be confused with]
  3. **Abuse potential:**

1. **Special Populations**: [include pertinent information for pregnancy, lactation, geriatrics, pediatrics, renal dysfunction, hepatic dysfunction]
   1. Pregnancy
   2. Lactation
   3. Geriatrics
   4. Pediatrics
   5. Renal Dysfunction
   6. Hepatic Dysfunction
2. **Storage:** [include any special storage instructions, light protection, beyond use dating if applicable]
3. **Operational Considerations:** [institute specific considerations such as **necessary monitoring parameters**, smart pump guardrails, epic med record, etc]
4. **Pharmacoeconomic Analysis:** [cost analysis and how use of the medication may impact the hospital economically. May present data in any organized fashion, but table below is one potential example]

**Table 3 (example): Estimated Budget Impact**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Drug** | **Dose (Treatment)** | **Cost/**  **Dose** | **Cost/**  **Patient /**  **3 day LOS** | **%**  **conversion to Drug B** | **No of patients receiving Drug B** | **Drug A cost** | **Drug B cost** |
| Drug A | Loading dose: 600 mg  Maintenance dose: 75 mg daily. | $36.79  $4.60 | $45.99 | *0%* | 0 | **$10,946** | $0 |
| Drug B | Loading dose: 60 mg Maintenance dose: 10 mg daily | $39.84  $5.21 | $50.26 | *10%* | 24 | $9,851 | $1,196 |
|  |  |  |  | *25%* | 60 | $8,209 | $2,990 |
|  |  |  |  | *50%* | 119 | $5,473 | $5,981 |
|  |  |  |  | *75%* | 179 | $2,736 | $8,971 |
|  |  |  |  | *100%* | 238 | $0 | **$11,962** |
| **Total extra expenditure (range)** | | | **$0 to $1016** | | | | |

1. **Insurance Coverage/Reimbursement:** [check common insurance websites, Medicare]
2. **Conclusions and Recommendations:** [summarize the key points of the monograph, weighing the pros and cons. Make sure to include recommendation for formulary addition and/or restriction]
3. **References:**

Cite references in numerical order of mention in the monograph. Use format in http://www.icmje.org/

**Clinical Trials:**

[In this section, include a small paragraph outlining the total number of trials you identified, indicate the types of studies and focus on the highest quality. This will help the reader understand the total volume of articles available and which were the highest quality. Rank in order of (1) comparative efficacy (2) randomized controlled trials (3) placebo-controlled trials; include the most pivotal trials and include quality of life data if available for high cost, low-to medium impact drugs]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study/Title/Journal | Study Design/Population Characteristics | Measures/Results | Adverse effects | Comments |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |