

Step Therapy & Utilization Management Medicine & Politics Converge

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“Fail First” Step Therapy

- The concept of “fail first” step therapy is pretty simple
 - The patient must first fail on an “inexpensive” drug before having access to the drug that is prescribed by the oncologist
 - The PBM/insurer administering the prescription drug benefit makes the determination of what the “fail first” drug is
 - Questions of whether the “fail first” drug is really the least expensive drug or the most profitable (translation, most profitable because of rebates) for the PBM/insurer
 - It’s essentially “cookbook” medicine (one size fits all)
- “Fail first” step therapy is not new
 - Many states now have laws to curb the use of step therapy to protect patients

The Politics of Step Therapy

- Trump administration (HHS) has given Medicare Advantage plans the power to use step therapy and formulary utilization management to lower drug costs
- Target is Medicare Part B drugs
 - Trump administration trying to give Medicare Advantage plans the hammer to negotiate (decrease) Part B drug prices
- Safeguards in place to protect patients
 - MA plans must disclose what plans include step therapy
 - Patients can appeal if they need a specific drug subject to “first fail”

Step therapy: The Oncologist Perspective

- Arbitrary
- Often inferior
- Difficult to evaluate
- Antithetical to personalized medicine
- Potentially harmful to patients
- Totally lacking consideration of the patient experience and patient related costs
- Administrative burden on the patient and the practice

The case of Denosumab

Insurer	Indication	Step Rx required	Condition for Denosumab	Comments
Humana	MM or solid tumor w bm	Pam or Zol	Disease prog, intolerance, contraind	Prostate Ca exempt
BCBS	Breast Ca prevent SRE	Pam or Zol	Ineffective, not tol, contraind	
	Solid Tumor Prevent SRE	IV Bis	Ineffective, not tol, contraind	
Cigna	Solid tumor bone mets prevent SRE	Zol	Hx of response to denosumab OR Failure/NR, contraind, intol or not a candidate	
Aetna	MM or solid tumor w bm; Hypercal malig	None	Medically necessary	
UHC	MM or solid tumor w bm	IV Bis	Refractory (w/in 30 d), contra, intol	1 yr max

Humana

“Patient centered care coordination”

Began January 1, 2019

Humana Non-Preferred Agent/s <i>Require conditions, drug failure, intolerance or contraindication of Preferred Agent/s for Prior Authorization</i>	Humana Preferred Agent/s 1st “Step” Requirement
Lutathera (lutetium Lu 177 dotatate) – Medicare, Commercial	Somatuline Depot OR Sandostatin LAR
Somatuline Depot (lanreotide) - Medicare, Commercial	Sandostatin LAR Depot
Marqibo (vincristine sulfate liposome) – Medicare, Commercial	vincristine sulfate
Doxil (doxorubicin liposomal) – Medicare, Commercial	doxorubicin Directed toward breast cancer, Hodgkin
Xgeva (denosumab) – Medicare, Commercial	zoledronic acid OR pamidronate
Granix (tbo-filgrastim) – Medicare, Commercial	Neupogen AND Zarxio
Abraxane (nab-paclitaxel) – Medicare	paclitaxel OR docetaxel Exception: pancreatic cancer
Epoetin alfa (Procrit, Epogen, Retacrit) – Medicare, Commercial	Retacrit (is now available)