

# Miacalcin Injection Use at Hilo Medical Center

# Postmenopausal Osteoporosis

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Differences in preparations, injection vs. intranasal:

- The absorption of the nasal dose is delayed compared with the parenteral route.
- The administration of salmon calcitonin is frequently associated with side effects such as nausea, vomiting, and flushing; these side effects are much less common with the nasal route.
- Nasal salmon calcitonin may provide more effective analgesia than parenteral salmon calcitonin.

Thus, the convenience and freedom from side effects make nasal salmon calcitonin the preferred route of administration in patients who can tolerate and cooperate with intranasal administration

# Background

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Trends in US Miacalcin expenditures and HMC

	2013	2014	2015
<b>Total USA</b>	<b>\$2,372,551.94</b>	<b>\$12,529,284.26</b>	<b>\$55,226,841.19</b>
<b>HMC</b>	<b>\$1633.00</b>	<b>\$12,553.00</b>	<b>\$17,373.00</b>

HMC followed national trend of increasing Miacalcin costs.

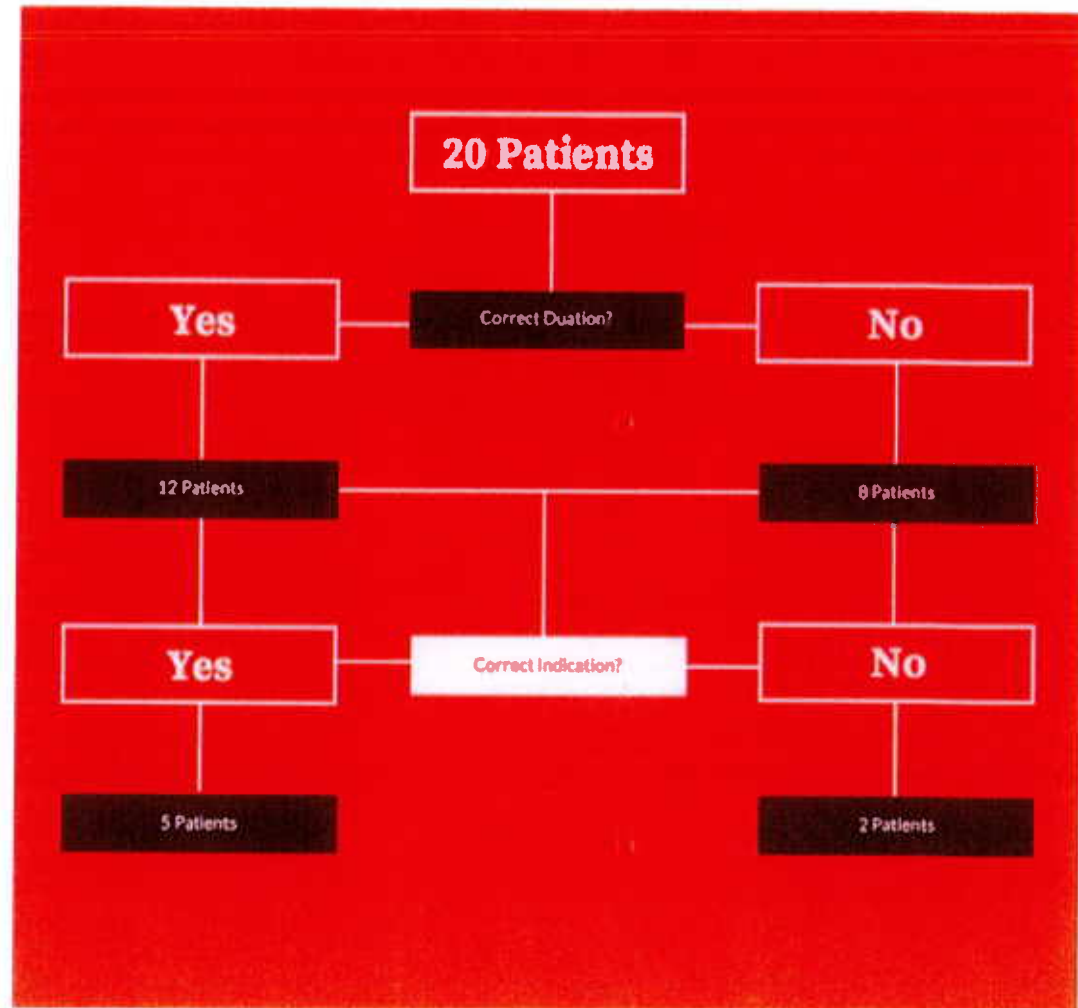
# Pharmacokinetics & Pharmacodynamics

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- **Onset of action** (Hypercalcemia): IM, SubQ: ~2 hours
- **Duration** (Hypercalcemia): diminishes within 24 to 48 hours
- **Bioavailability:**
  - IM: 66%
  - SubQ: 71%
  - Nasal: ~3% to 5%
- **Half-life:**
  - IM: 58 minutes
  - SubQ: 59 to 64 minutes
  - Nasal: ~18 to 23 minutes
- **Time to peak:**
  - SubQ: ~23 minutes
  - Nasal: ~10 to 13 minutes

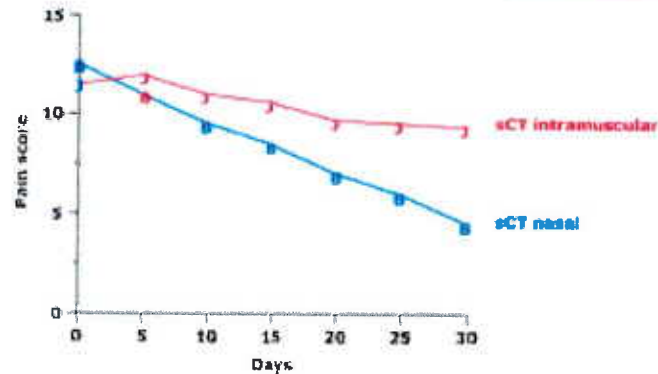
# Data Review

- Baseline Characteristics
  - Sex, age
- 20 patients
  - 8 patients incorrect duration (> than 48 hour duration)
  - 5 patients incorrect indication



## Nasal Calcitonin for osteoporosis:

### Nasal versus intramuscular calcitonin for bone pain



Intranasal showed more effective pain relief

Effect of salmon calcitonin on spontaneous bone pain in patients with recent osteoporotic fractures treated with either intranasal (100 international units) or intramuscular (100 international units) calcitonin. The intranasal calcitonin led to more effective pain relief.

sCT: salmon calcitonin.

Data from: Gennari C, Agnusdei D, Camporeale A. Use of calcitonin in the treatment of bone pain associated with osteoporosis. *Calcif Tissue Int* 1991; 49 Suppl 2: 59.

## Miacalcin Expenses:

Miacalcin Expenditures during review period:  
July 2017 to August 2018

**Purchased 75 units at \$185,895.00**

Since 2013 price has increased by about 4000%  
(\$62 vs \$2625 per vial)

# Evaluation Criteria

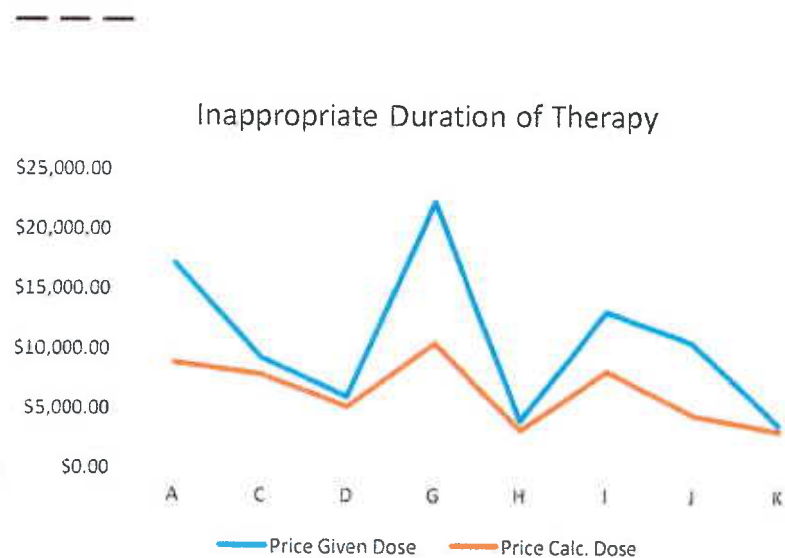
Criteria used during Drug use evaluation:

Hypercalcemia:

- Mild Hypercalcemia (calcium < 12 mg/dL)
  - DO NOT REQUIRE IMMEDIATE TREATMENT
- Moderate Hypercalcemia (calcium 12 - 14 mg/dL)
  - DO NOT REQUIRE IMMEDIATE TREATMENT
- Severe Hypercalcemia (calcium > 14 mg/dL) → IMMEDIATE TREATMENT REQUIRED
  - DOSE & FREQUENCY
    - IM, SubQ
      - 4 units/kg every 12 hours; if response is unsatisfactory after 24 hours, may increase to 8 units/kg every 12 hours
      - Correct dose determined by  $\pm$  50 units
  - DURATION
    - 48 hours due to hypocalcemic effect of calcitonin diminishing (tachyphylaxis) after 24 to 48 hours



# Results - Inappropriate Duration of Therapy



Patient	Price Given Dose	Price Calc. Dose
A	\$17,056.00	\$8,711.68
C	\$9,184.00	\$7,767.04
D	\$5,904.00	\$5,038.08
G	\$22,304.00	\$10,391.04
H	\$3,936.00	\$3,148.80
I	\$13,120.00	\$8,081.92
J	\$10,496.00	\$4,408.32
K	\$3,608.00	\$3,096.32
<b>Total:</b>	<b>\$85,608.00</b>	<b>\$50,643.20</b>
		<b>➔ Potential Saving: \$34,964.80</b>

Chart shows cost of Miacalcin used in 8 cases vs cost of Miacalcin if discontinued after 48 hours.

## Summary:

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1. Tachyphylaxis develops to Calcitonin's hypocalcemic effects usually diminishes after 48 hours.
2. P&T committee has approved a default stop time of 48 hours for Miacalcin injection.
3. Calcitonin nasal spray is effective in postmenopausal osteoporosis and should be consider before use of the injectable form.
4. HMC could reduce Miacalcin expenses by \$40,000.

# Miacalcin (calcitonin - salmon)

- **Hypercalcemia:** 4 units/kg SUBQ or IM every 12 hours; if response is unsatisfactory after 24 hours, may increase to 8 units/kg every 12 hours
- **Postmenopausal osteoporosis:** 100 units IM, SubQ daily; 200 units (one spray) in one nostril once daily

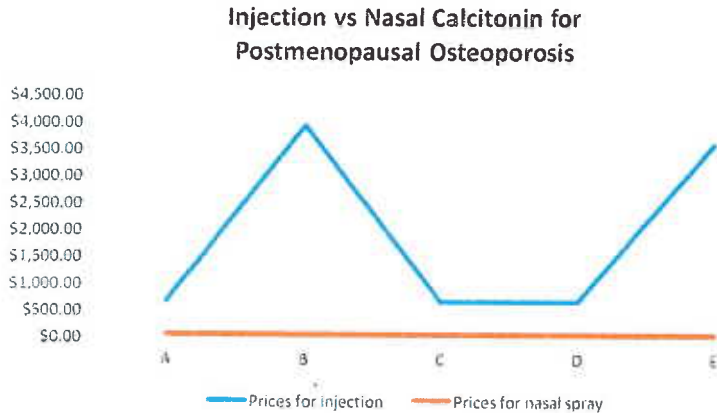


## Tachyphylaxis:

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- American society of clinical Oncology: Calcitonin is also used to acutely lower calcium levels. When used with bisphosphonates, it can lower calcium more rapidly than either agent alone. Unfortunately, tachyphylaxis can occur within 48 hours as a result of downregulation of the calcitonin receptors
- Up To Date: The efficacy of calcitonin is limited to the first 48 hours, even with repeated doses, indicating the development of tachyphylaxis, perhaps due to receptor downregulation. Because of its limited duration of effect, calcitonin is most beneficial in symptomatic patients with calcium  $>14$  mg/L (3.5 mmol/L), when combined with hydration and bisphosphonates. Calcitonin and hydration provide a rapid reduction in serum calcium concentration, while a bisphosphonate provides a more sustained effect

# Results - Inappropriate Indication of Therapy



Patient	Prices for injection	Prices for nasal spray (total of 30 doses)
A	\$656.00	\$38.51
B	\$3,936.00	\$38.51
C	\$656.00	\$38.51
D	\$656.00	\$38.51
E	\$3,608.00	\$38.51
<b>Total:</b>	<b>\$9,512.00</b>	<b>\$192.55</b>
<b>➔ Potential Saving: \$9,319.45</b>		

Cost of Miacalcin in 5 osteoporosis patients using injection vs cost if Nasal calcitonin was used.

# References

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1. Camacho P M, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis -2016. *Endocr Pract.* 2016; 22(Suppl 4):1-42.
2. Lexicomp Online, Lexi-Drugs, Hudson, Ohio: Lexi-Comp, Inc.; September 1, 2018
3. Micromedex Solutions, Ann Arbor, MI: Truven Health Analytics, Inc.; September 1, 2018
4. Novartis Pharmaceuticals Corporation. (2018). Miacalcin: Highlights of prescribing information. Retrieved from [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/210491lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210491lbl.pdf)
5. Pollack, Richard J., American Hospital Association. Trends in hospital inpatient drug costs: issues and challenges. Retrieved from <https://www.aha.org/system/files/2018-01/aha-fah-rx-report.pdf>