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**Appendix 6:
Summary of ONJ Cases from Retrospective Chart Review at
MD Anderson Cancer Center**

Zometa[®] (zoledronic acid) Injection

and

Aredia[®] (pamidronate disodium) Injection

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Oncologic Drugs Advisory Committee Meeting

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Summary of ONJ Cases from Retrospective Chart Review at MD Anderson Cancer Center

ID	Gender/ Age	Diagnosis	Date of DX	BP (Type/#)	Date of DX ON	BP Duration (mos)	Predisposing factors	Clinical presentation	Onco Treatments
1 (A)	F/54	MTC, hypothyroidism	12/97 Bone mets 5/99	Aredia 4/00 qmo In 2003 was on Zometa (date N/A) Rx'd in Georgia	01/03	<u>33mos</u> A: 33mos (Z: N/A)	Trauma to jaw/anesthesia in 12/02	Trauma never healed 10/03 pain right mandible with exposed bone Progressive with extension to maxilla	DTIC Anti-CEA antibody/Adria
2 (AZ)	M/58	MM, COPD, HTN, DM, smoking	10/96	MDA pharmacy A - 1/98-2/02 Z - 3/02-9/04	09/02	<u>57 mos</u> A: 50 mos Z: 7 mos	Gingivitis 6/02 Dental decay 6/02 Periodontal dz 6/02 Dental Extraction 7/02 (7 teeth) Dentures XRT to maxilla 7/02	Right maxilla pain and poor healing/exposed bone 9/02 3/03 several areas of exposed bone 6/03 necrotic bone 9/03 larger areas 4x2 cm bilaterally + ant. bone exposure 1/x0.5 cm-debrid. 10/03, 11/03 debridements	Melphalan, prednisone, decadron hyper/cvad, interferon, thiohepa, busulfan, cyclophosphamide, thalidomide, arsenic autologous BMT X2 lanoxin, vioxx, protonox, codeine, xanax, klonopin, prilosec, buspar, hydrocodone
3 (AZ)	F/79	MM, DVT, HTN	5/01	A - 5/01 - 6/02 Z - 7/02 - 4/04 *see CRF	8/03	<u>26 mos</u> A: 13 mos	Several dental extractions 9/02 Mandibular tori	Pain left mandible 8/03 (2x1 cm lesion) Debridements 8/03, 10/03,	Melphalan, DEX, cyclophosphamide, cytoxan, thalidomide, coumadin, velcade, procrit, darbepoetin

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						Z: 13 mos		11/03, cephalexin, clindamycin, 1/04 worse ON 4/04 1/5 cm lesion	
4 (AZ)	F/47	MM, DM, Renal failure	3/97	A - ? Z - ?	6/02	Unknown	Dental extraction in 6/01 tooth #20 left mandible 2/02 (outside MDA) – sequestrec- tomy to remove necrotic bone. Mod. Periodontal dz	Pain left mandible since 2/02 Panorex 6/02: lesion left mandible 2/03 debridement 3/03 hyperbaric O2 Rx 4/03 worsening of necrosis (1.5 cm) 9/03 stable	Hyper-CVAD (cytoxan, mesna, adryamycin, vincristine, decradron, cyclophosphamide, decadron, thalidomide, arsenic, melphalan, velcade.
5 (Z)	F/60	Breast ca, Bone mets 12/02	10/99	No A Z – 5/03-7/03	5/04	Z: 2 doses Latency 12 months	None	Pain right mandible/expose d bone (1x1cm) Biopsy: necrotic bone Sequestrectomy 5/04 Controlled with treatment	Aryamycin, Cyclophosphamide, Paclitaxel, Tamoxifen, Docetaxel, Arimidex, Exemestane, bellerga, xanax, elavil, melatonin, prilosec
6 (AZ)	F/70	Breast ca	1/30/98	A - 22 inf (90 mg q mo) Z – 28 infus.	4/04	<u>45 mos</u>	Dental extraction Dentures	Pain right mandible, Poor healing, exposed	5-FU, adryamycin, cyclophosphamide, tamoxifen, arimidex, exemestane,

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				(4mg q mo) 5/02 A – 8/00-4/02 Z – 5/02-9/04 (22 doses of A, 28 doses of Z)		A: 21 mos Z: 24 mos		bone – Infection?	capecitabine, TAS-108, vinorelbine, gleevec, trastuzumab, paclitaxel 01/03-4/03, dexamethasone 10mg weekly 01/03
7 (AZ)	M/67	MM, osteoporosis	8/98	A-7/99 – 4/02 Z-6/02 – 9/04	2/04	<u>53 mos</u> A: 32 mos Z: 21 mos	Moderate periodontal disease Mandibular Tori	6/99: good dentition 2/04 - pain right mandible: 3mmX4mm bone exposure 6/04: lesion healed	Hyper-CVAD (1/99) autologous BMT (6/99) Serial dex 8/99 Thalidomide + dexamelphalan Revimid
8 (Z)	F/42	Breast ca	9/98	Zometa started 10/03 with DX of bone mets	5/04	<u>7 mos</u> Z: 7 mos	Dental extraction (1/04), Torus mandibularis, Slow healing and dry socket after extraction	Pain tooth #30, Poor healing, Infection, Bone exposure right mandible 5/04	Cytosan, 5-Fu, methotrexate, tamoxifen, evista, adryamycin/ cytozan, Taxol (7/03), Arimidex, Faslodex (5/7/04), Prozac, bextra, ambient, cipro, calcium, clindamycin, vicoprofen, XRT chest wall 1999, XRT mediastinum 12/01
9 (AZ)	F/44	Breast ca	10/99	A: 11/00 – 2/02 Z: 12/01 – 8/03	11/02	<u>27 mos</u> A: 16 mos	Mandibular Tori	12/99 – dental visit: mand. tori 11/02: pain right mandible –	Paclitaxel, FAC, tamoxifen, Herceptin (11/02), navelbine, xeloda,

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9 cont.						Z: 11 mos		exposed bone 4/03: stable 10/03: stable 11/03: necrotic area larger 12/03: debridement	dexamethasone (10/01 XRT: left hip, WBRT, Lspine, chest wall, axilla
10 (A)	M/60	MM	1/99	A: 1/99-4/00	5/99	<u>4 mos</u> A: 4 mos	Bone exostosis, Dental extraction 5/99, Periodontal disease 5/99, smoking – 34 years	5/99: exposed bone after dental extraction (no pain) in maxilla and mandible; Treated with debridement and antibiotic: resolved 4/04.	Dexamethasone, Cytosin, Melphalan, Holmium, Pepcid, Valium
11 (A)	F/61	Breast cancer	4/92	A : 3/99 – 12/01 Z: 4/02-5/03	8/00	<u>17 mos</u> A: 17 mos	Dentures, Dental decay, Periodontal disease, Dental extraction 5/00 with poor healing	8/00: gum pain, exposed bone left mandible and maxilla Controlled with treatment	FAC '92, Methotrexate '92, Vinblastine '92, Tamoxifen 10/99, Exemestane 2/01, Fulvestrant 8/02, Megestrol 6/04, MVI, Celebrex, Hydrocodone
12 (AZ)	F/69	Breast ca, Melamona 1962, Bone mets 9/00	10/97	A: 11/00-7/02 Z: 8/02-9/04	11/04	<u>46 mos</u> A: 21 mos Z: 25 mos	Dental decay 5/04, Dental extraction 5/04	Poor healing after extraction, infection, no pain, exposed bone (11/04) left mandible	Tamoxifen 3/98, Anastrozole, Vioxx, Hydrocodone, Lasix, Bactrim, Clindamycin

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13 (AZ)	F/46	Breast ca	7/01 Bone mets	A: 8/01-11/02 Z: 11/02-10/04	8/04	<u>37 mos</u> A: 15 mos Z: 22 mos	Gingivitis, advanced periodontal DZ, dental infection	8/04: pain right mandible, spontaneous bone exposure	Taxol 9/01, Herceptin 2/02, Taxoxifen 2/02, Prilosec, Decadron, Darvon
14 (AZ)	F/61	Breast ca, hypothyroidism	2/00 bone mets	A: 2/00-10/02 (~37 doses) Z: 11/02-10/04 (~23 doses)	10/04	<u>58 mos</u> A: 34 mos Z: 24 mos	Gingivitis, Manipulation of right mandible, implants with poor healing and infection	4/04: right mandible pain – bone exposure 9/04: mand. implants removed, 10/04: 2X1x1.5cm bone exposure site, Healing well with irrigation, slicept	Tamoxifen, arimidex, celebrex
15 (Z)	F/71	MM, DM, Hyperlipidemia, ETOH use	1/00	Alendronate (4/00-11/01) Z: 4/03, 7/03, 8/03, 11/03, 1/04	6/04	5 doses, latency 14 months	Dentures (traumatic wound)	Gum/jaw pain 4/04, Gingivitis, osteomyelitis, bone exposure 6/04: Eikenella corrodens, Rx'd 7/04: 2X1cm 8/04: debrid 11/04: 0.2X0.7cm	*steroids – induced diabetes Dexamethasone 9/00, Valcade 4/03, Revimid 4/03, Interferon 9/00, Vioxx, Prevacid, Lortab, Zocor, Zolof, Xanax, Neurontin
16 (AZ)	F/60	Breast ca, melanoma	5/80 bone mets 2/99 last visit to MDA: 9/04 (dead)	A: 3/99-10/01 Z: 12/01-6/04	12/03	<u>56 mos</u> A: 31 mos Z: 25 mos	Periodontal dz, Dental extraction 6/03, slow healing 7/03 *Rx'd with	7/03 slow healing: debridement 8/03: debridement 12/03: bone	XRT: chest, nodes, L- spine, and brain 7/04. Taxotere 3/99, Cytosan 3/99, Cyclophosphamide

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							clindamycin, salicept, debridement	exposure 2/04 dental at MDA: ONJ 2.5x2cm right mandible (biopsy proven) ¾ : 3/2 cm- debridement ¾ healing 5/04: debridement 6/04: healing	3/99, Adriamycin 3/99, Tamoxifen 6/99, G-CSF 6/99, FEC 5/01, Xeloda 5/01, Aptosyn 5/01, Navelbine 8/01, Gemcitabine 8/01, Doxil 5/02, Faslodex 5/03, CPT-11 6/04, CMF 6/04, Augmentin, Cipro
17 (Z)	F/78	Breast ca, Osteoporosis, Atrial Arrhythmia, anemia	4/83 bone mets 8/02	Z: 9/02-1/05 (qmo)	10/04	<u>26 mos</u> Z: 26 mos		Being treated outside MDA??	Femara, Tamoxifen, faslodex
18 (Z)	F/63	Breast ca, degenerative joint disease, asthma	10/02 bone mets 11/02	Z: started 4/03 outside MDACC Last Zometa qmo. @MDACC 2/04	12/04	<u>9 mos</u> Z: 9 mos	Periodontal disease and tooth extraction 2/04	Facial pain and swelling. Extraction of tooth root 10/04, pain/swelling and purulent drainage @ extraction site 12/04, poor fitting denture – trauma 12/04, osteomyelitis left maxilla 12/04.	Femara 10/02, Capecitabine 7/03, Adriamycin 1/04, Cytosaxan 1/04, Fasoldex 7/04, Albuterol, Wellbutrin, Singular, Equagesic, Aleve and Cipro