Department of Endocrine & Breast Surgery
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, India

Evidence-Based Pragmatic
SGPGI Breast Cancer Management Protocols (Summary)

Background:
Breast cancer management in country like ours with resource limitation and uneven income distribution has to be approached differently from the industrialized world. The stage at disease presentation and pathology are different, so are the socio-economic compulsions of the patients, necessitating emphasis on efficacious, yet safe and cheap management strategies. A pragmatic approach to individual breast cancer patient based on sound scientific evidence, yet keeping the socio-economic realities and infrastructural and manpower compulsions of SGPGI have been worked out over period of many years. Guidelines from various professional bodies, meta-analysis, systematic reviews and RCT's, along with interpretations of contemporary data from faculty and residents of this department as also of collaborating departments of Radiation Oncology, Pathology, Nuclear Medicine and Radio-diagnosis have formed the basis of these guidelines to a large extent. The first formal SGPGI Breast cancer protocols were formulated in late 2001. Since that time, two major revisions have been made. A summary of the third revised version of SGPGI Breast Cancer protocols is provided here.

Clinical presentation of breast carcinoma at SGPGIMS Lucknow include
Breast lump
- Usually painless progressive
- Occasional nipple discharge
- Ulcerated growth

Metastatic symptoms like weight loss, bone pain, jaundice or hemoptysis
Operated elsewhere (various degrees of surgical intervention)
Screen detected (rare)
Patients presenting for hospital based screening, out of concern for cancer usually have
- Breast pain
- Breast nodularity
- Women with family history

Patients referred for screening / evaluation before or during HRT

Approach to breast lump/ suspected breast malignancy
A detailed history including
- Number of off-springs and adequacy of breast feeding
- Menopausal status, history
- Onset, duration and progress of lump
- Associated nipple discharge
- History of trauma to breast, fever
- Use of HRT, OCP
- Family history of breast carcinoma, ovarian malignancy and other related tumors in first and second degree relatives,

Diagnostic investigation of a suspected malignancy
Triple test
- Clinical breast examination
- Fine needle aspiration cytology
- Mammography / USG breasts

* For patients having prior intervention elsewhere, review of the histology / cytology slides & Blocks

Based on the above initial workup, a cytologically proven or suspected breast cancer is staged clinically according to the ***TNM- AJCC 2002**** staging system of breast carcinoma
(* Refer to 6th edition of AJCC manual of TNM staging, also available in this course manual in later article)

Clinical stage grouping is done for ease of communication and management planning, as follows:

Early breast cancer - Small operable tumors (<5 cm), nodal status N0/N1, M0
Breast conservation possible
Large operable cancers - Large operable tumor (>5 cm), nodal status is N0/N1, M0
Prognosis is similar to stage II disease
Mastectomy is possible, breast conservation is difficult
Locally advanced breast carcinoma- mostly stage III disease: T4, N2/ N3, M0.
Considered inoperable, will require neo-adjuvant systemic treatment
Metastatic disease - Evidence of metastasis (other than regional lymph nodal metastases)
Treated with primary systemic treatment/ palliative measures alone

Investigative work-up after clinical staging:

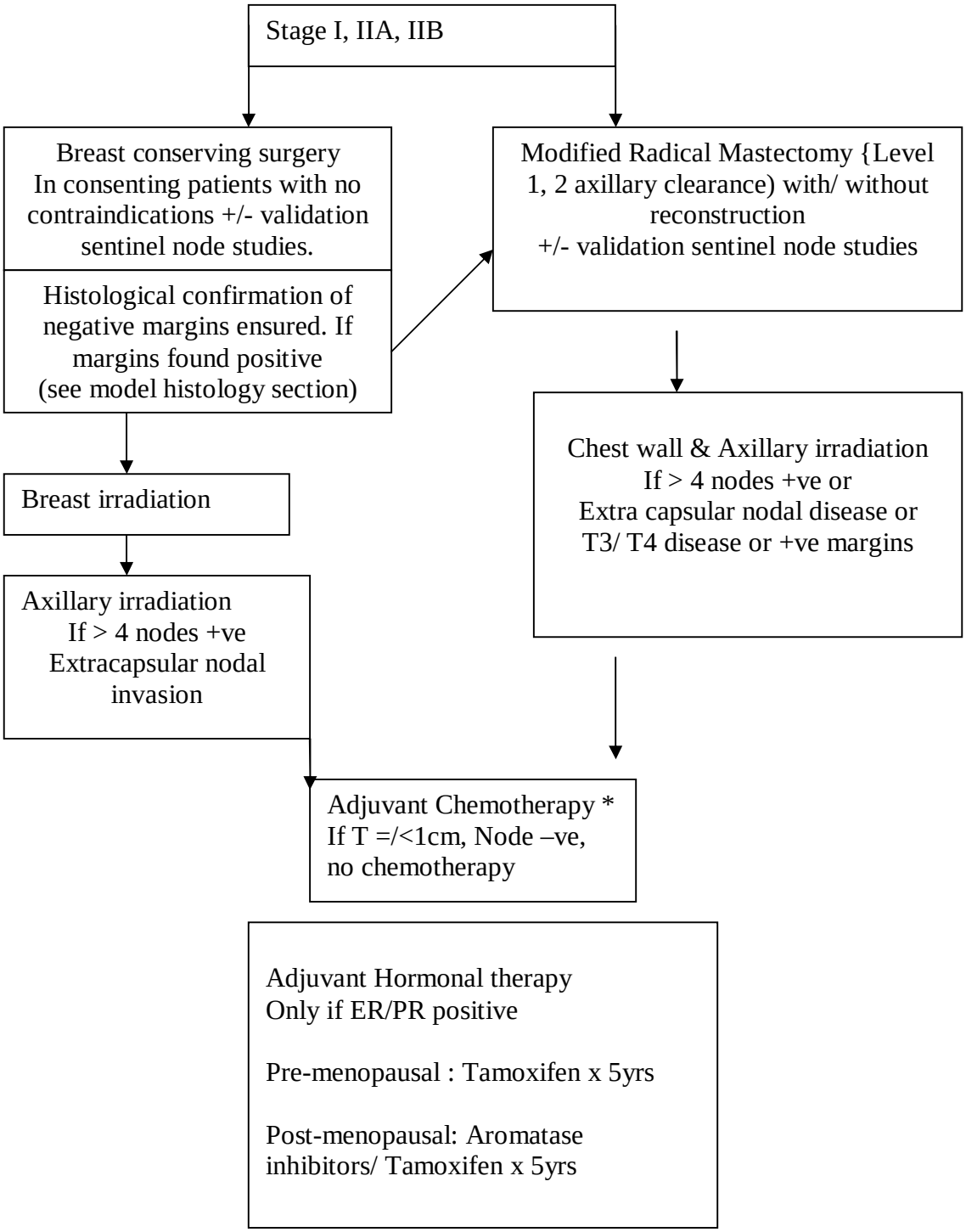
Following minimal metastatic workup after a working diagnosis and staging is done. In selected patients, other symptoms/ signs directed test may be employed

X ray Chest- PA view
Blood chemistry including serum Alkaline phosphatase, LFT
Mammography if not done earlier.
If >T2 or >N1 disease, symptomatic, raised serum alkaline phosphatase- also include
-^{99m}Tc MDP Skeletal Scan
-USG abdomen- to look for metastatic deposits

Clinical staging is upgraded with any added information from imaging.

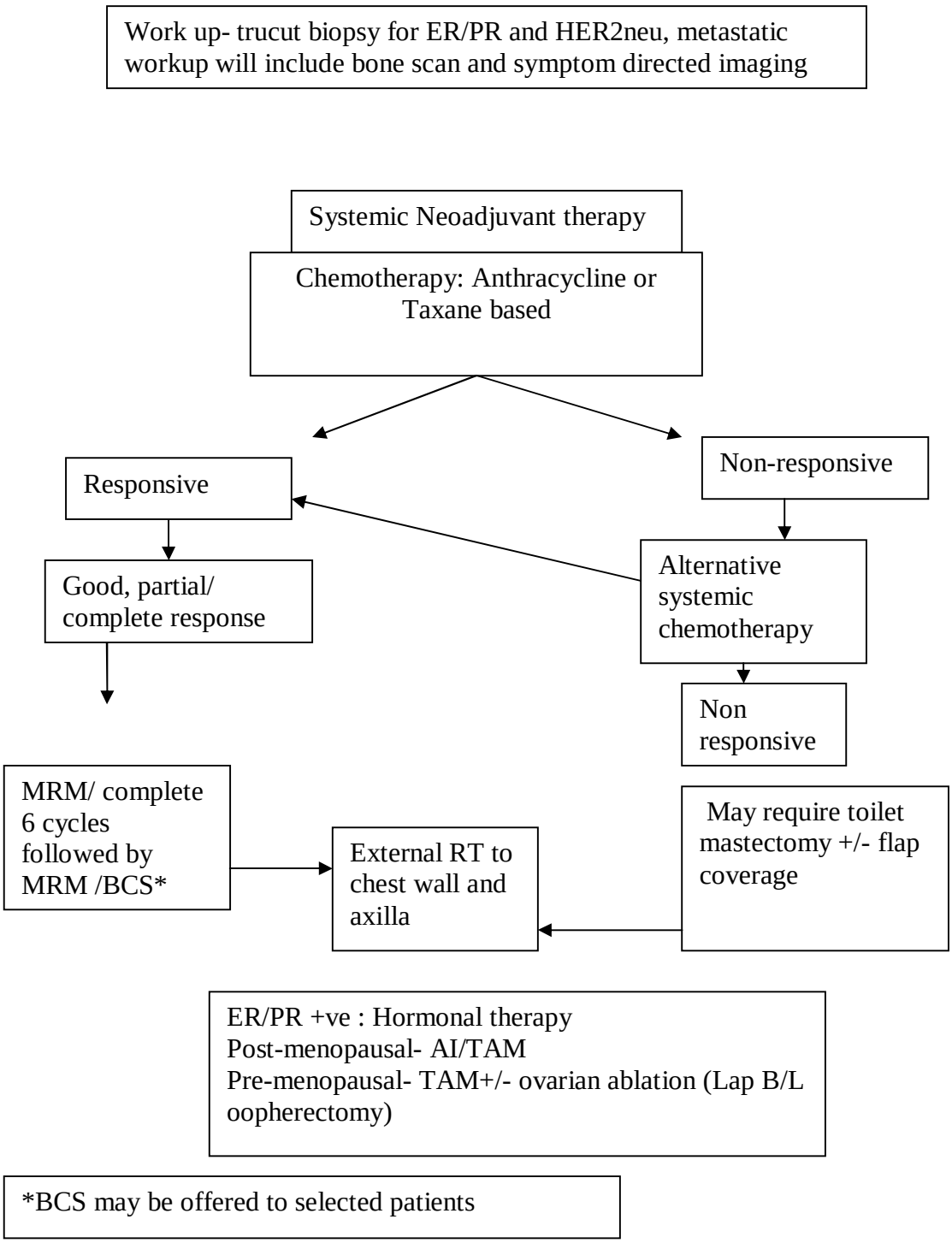
Treatment protocol for early breast cancer

Early breast cancer- T1/T2, N0/N1, M0 disease
Stage I, IIA, IIB (T2N1)

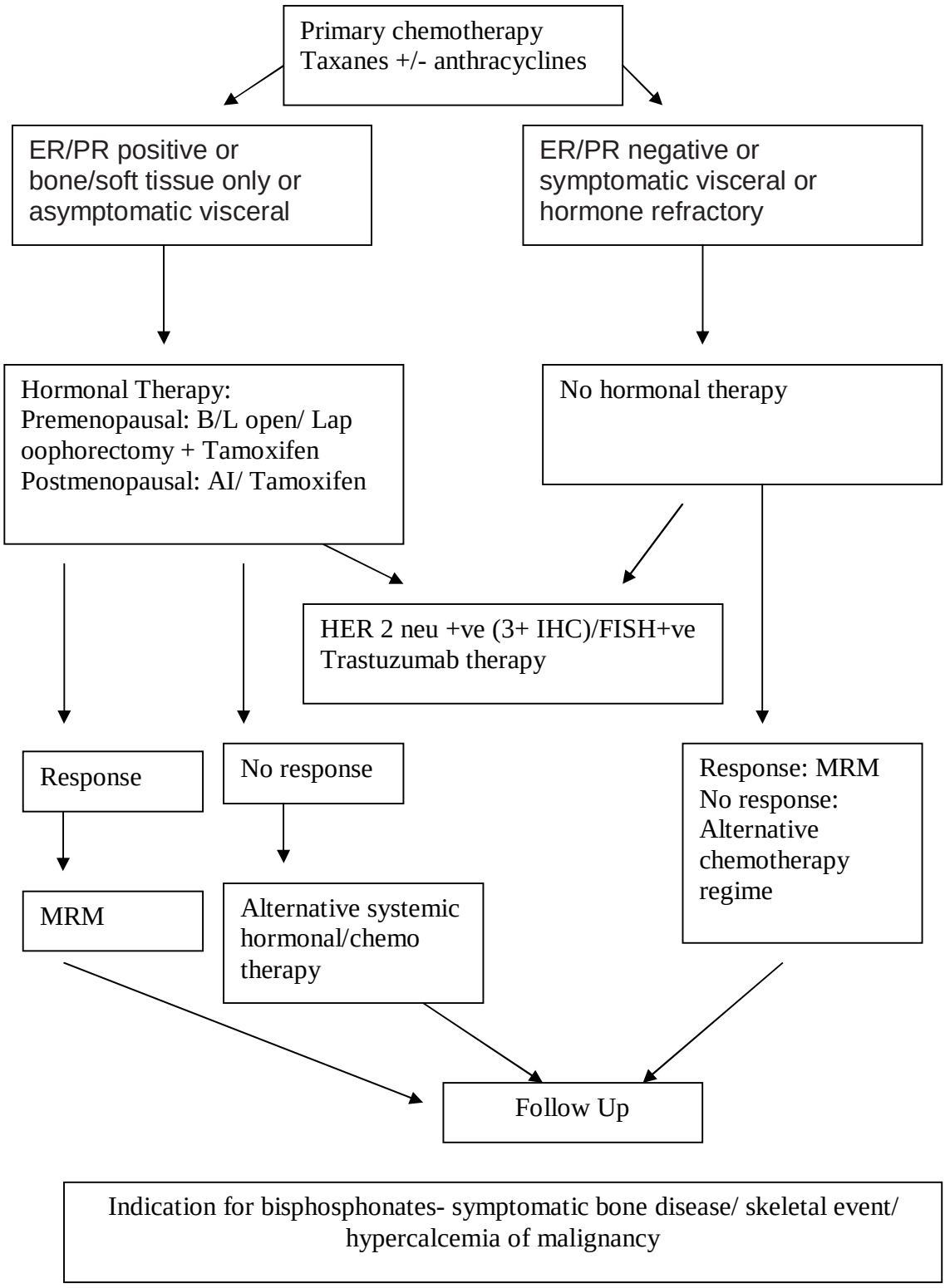


Treatment protocol for locally advanced breast cancer

Locally advanced (and Large operable) breast cancer- Stage IIIA, IIIB, IIIC, and IIB (T3N0M0)



Treatment protocol for Metastatic Ca Breast:



Chemotherapeutic regimen and agents used commonly:

Regimen	Cycle interval	Drugs	Dose
CAF	q 21 d	Cyclophosphamide	600mg/m2 IV Day 1
		Doxorubicin	60mg/m2 IV Day 1
		5 Flurouracil	600 mg/m2 IV Day 1
CEF	q 21 d	Cyclophosphamide	500mg/m2 IV Day 1
		Epirubicin	100mg/m2 IV Day 1
		5 Flurouracil	500mg/m2 IV Day 1
AT	q 21 d	Adriamycin	60mg/m2 IV Day 1
		Docetaxel	100mg/m2 IV Day 1
TAC/ TEC	q 21 d	Docetaxel	100mg/m2 IV Day 1
		Doxorubicin/ Epirubicin	50mg/m2 IV Day 1
		Cyclophosphamide	500mg/m2 IV Day 1

Hormonal agents/ targeted therapy used:

Group	Drug	Dose
Antiestrogen	Tamoxifen	20mg PO OD
Aromatase inhibitors	Letrozole Exemestane	2.5mg PO OD
HER 2 monoclonal antibody	Trastuzumab	4mg/kg loading dose 2mg/Kg/week maintenance till disease progression/ 1yr/ critical toxicity appears

Follow up Protocol

First visit after completing the treatment (Surgery, chemo, and radiotherapy): starts 3 months after completion of treatment or 1 yr after initial evaluation which ever is earlier.

- Clinical breast examination
- Hemogram
- Blood chemistry incl s-ALP, LFT, Ca
- CA 15-3 (selective)
- X ray chest
- ECG/ECHO to r/o CT/RT toxicity
- Bone mineral densitometry

6 months post treatment:

- Clinical breast examination
- Alk PO4
- X ray chest PA
- Symptom/ chemistry directed tests

1 year after completing initial treatment

- Clinical breast examination
- Blood chemistry incl S Calcium, Alk PO4
- X ray chest PA
- Mammogram
- USG abdomen
- Tc 99 MDP Bone Scan

Model histology report includes

Patient name	Age/sex	Central registration number
Side - Left/Right	Date of reporting	
Type of specimen	Breast specimen- Wide local excision/Segmental excision/Mastectomy Axillary Specimen- Axillary clearance/Axillary sampling/Sentinel node(s)	
Gross Histology	No of lesions/Size of lesion/Site of lesion No of nodes dissected/grossly significant nodes/Sentinel nodes (no of blue/hot/both blue and hot)	
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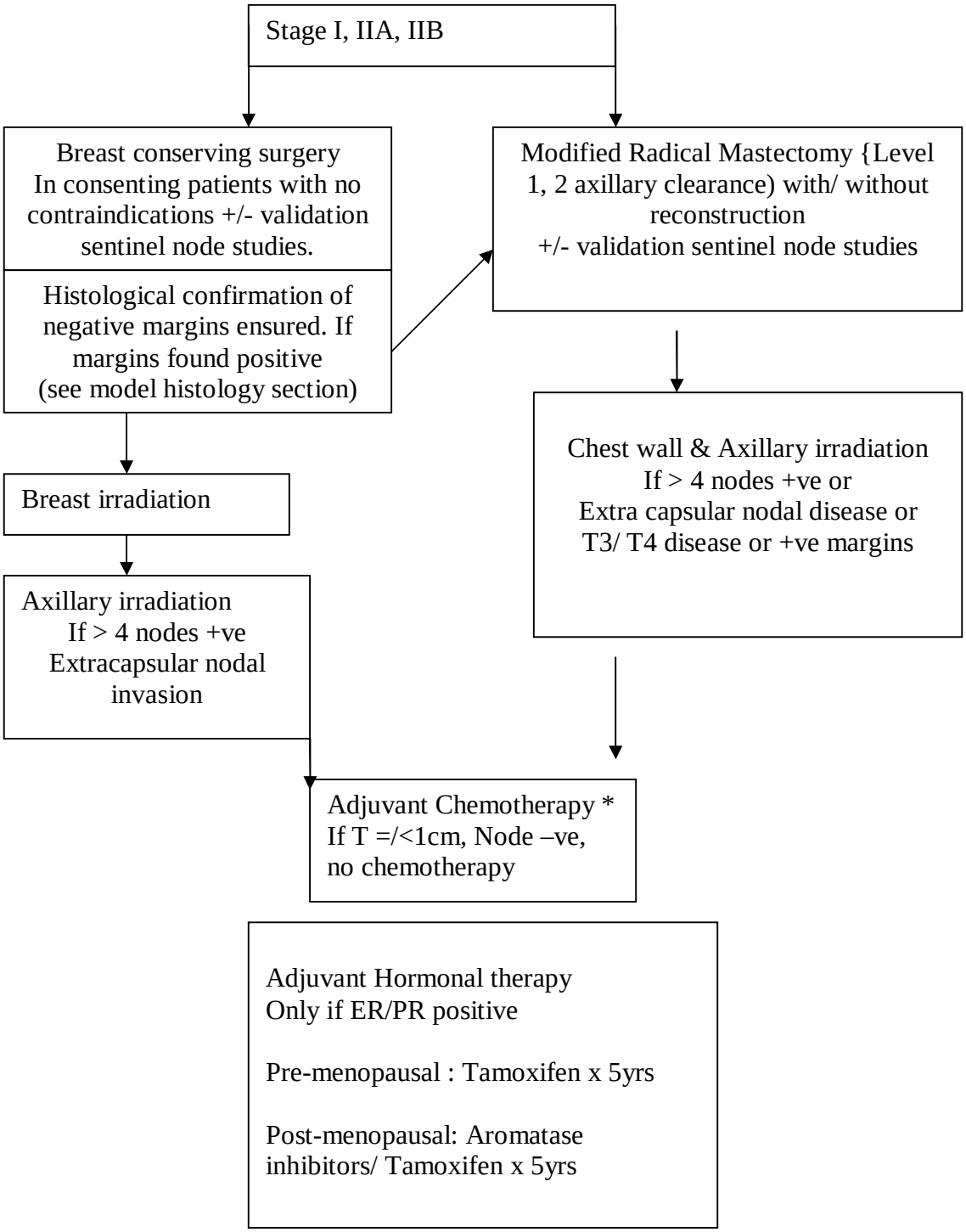

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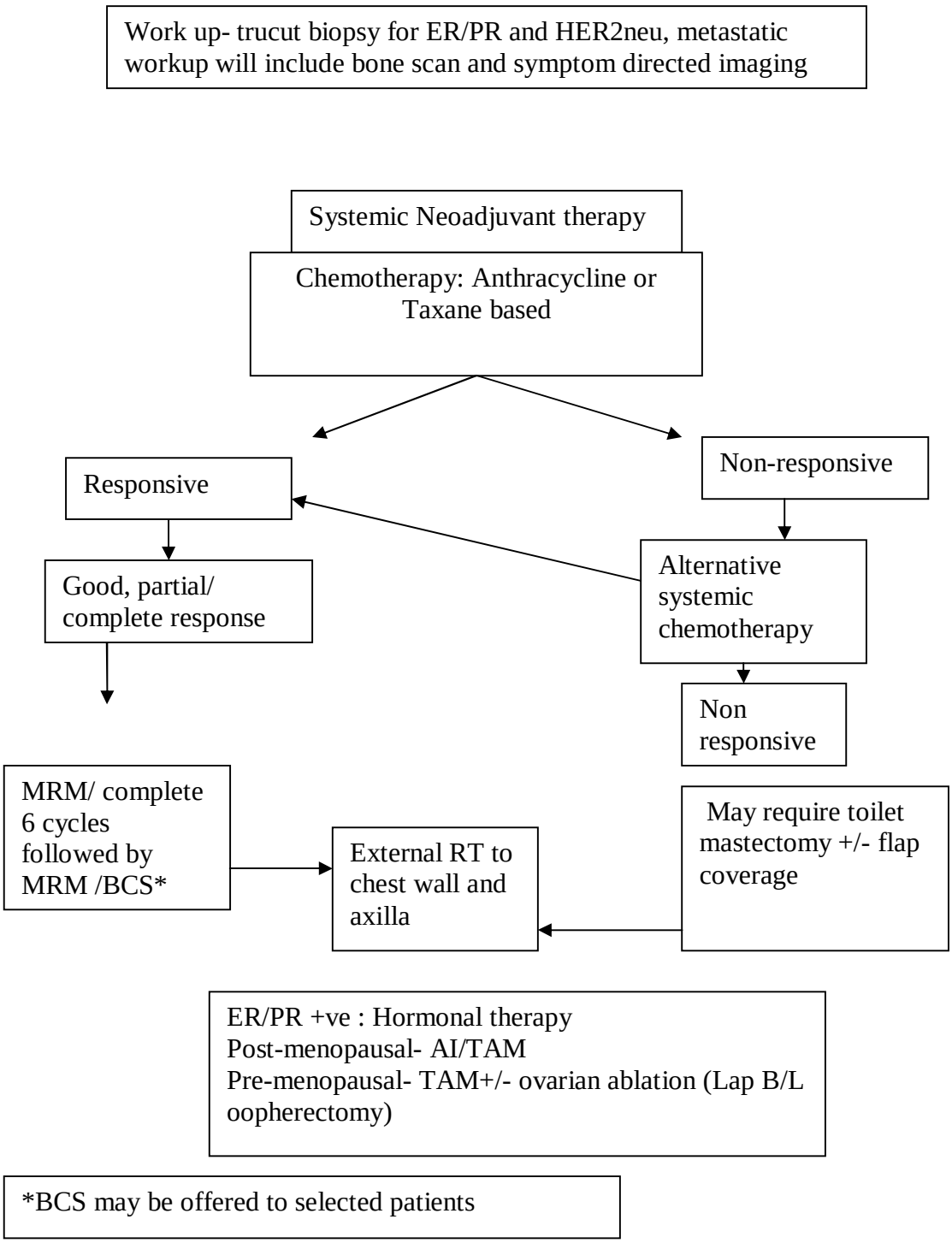

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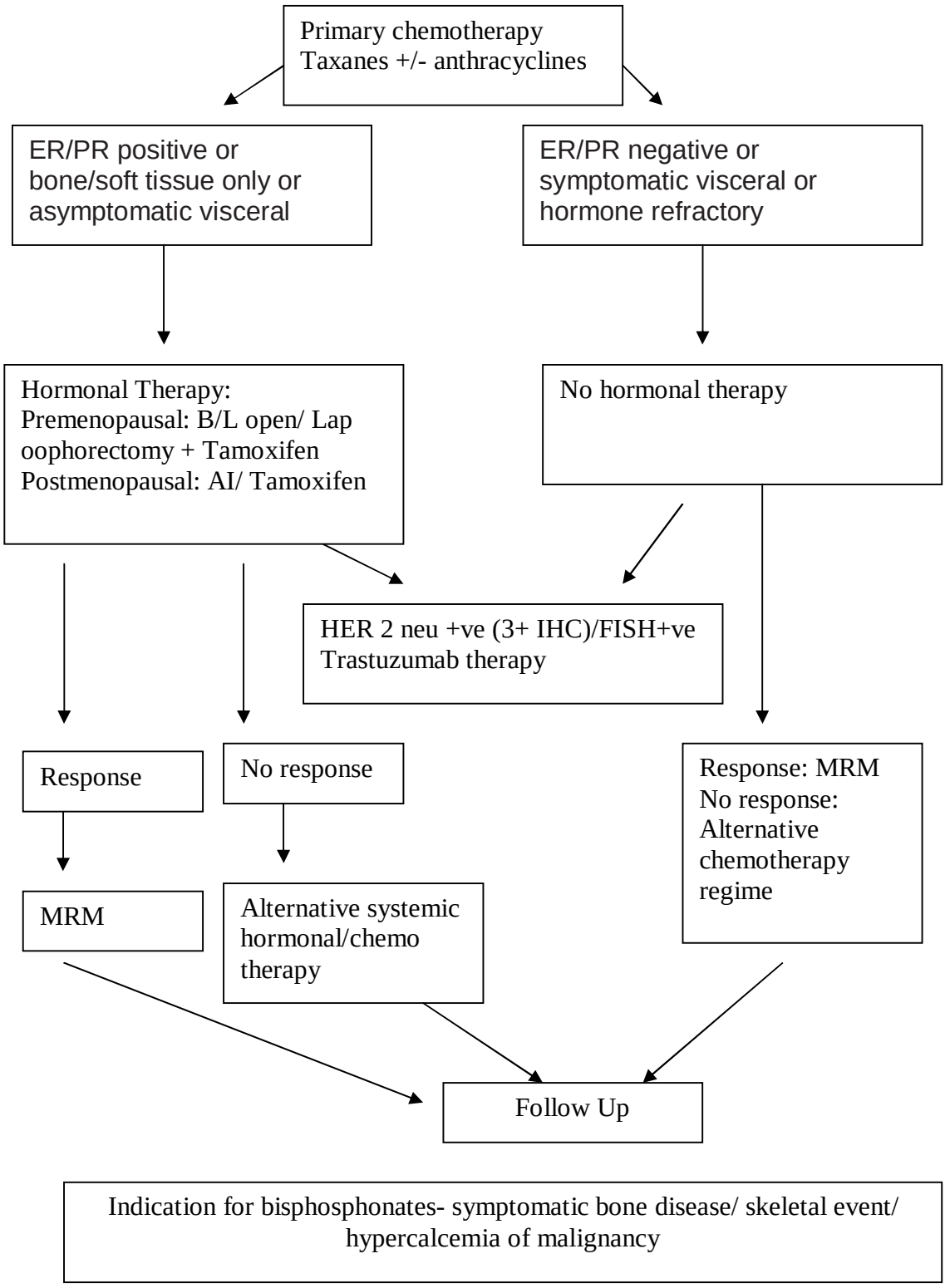

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