

# 高雄榮民總醫院 神經母細胞瘤診療原則

2023年03月28日第一版

兒童癌症醫療團隊擬訂

注意事項：這個診療原則主要作為醫師和其他保健專家診療癌症病人參考之用。假如你是一個癌症病人，直接引用這個診療原則並不恰當，只有你的醫師才能決定給你最恰當的治療。

# 修訂指引

- 本共識依下列參考資料制定版本
  - 台灣兒童癌症研究群(TPOG)  
TPOG N2020 potocol V1(2021/1/18)

# 會議討論

上次會議：2022/03/15

本共識與上一版的差異

上一版	新版
1.TPOG N2020版本無新增或修改protocol，故2022年僅審視未修。	1.放上Assignment of Risk Group Protocol表格(ppt.5)。 2.放上maintenance therapy表格(ppt.20、21、23)。

## ◎危險群分類

1. Very Low Risk : Stage L1, any age, without MYCN amplification,  
Stage MS, without MYCN amplification and 11q deletion, without LTS
2. Low Risk : Stage L2, any age , without MYCN amplification and 11q deletion  
Stage M, age < 18m, without MYCN amplification, but with hyperdiploid  
Stage MS, without MYCN amplification and 11q deletion, with LTS
3. Intermediate Risk: Stage L2, any age, without MYCN amplification, but with 11q deletion  
except age > 5y with undifferentiated/poor differentiated type  
Stage M, age < 18m, without MYCN amplification, but with diploid
4. High Risk : Any Stage, any age, with MYCN amplification  
Stage M, age  $\geq$  18m  
Stage L2, age > 5y with undifferentiated/poor differentiated type
5. Perinatal : Stage L1, age < 3m

§ LTS: life threatening symptoms

§L1/L2: 依INRG stage

- INRG stage (包括image defined risk factor<IDRF>)及LTS見以下ppt說明

## ◎Assignment of Risk Group Protocol

INGR Pre-Treatment Classification

INGR Stage	MYCN	Age	Histological Category/ Grade of Tumor Differentiation	11q deletion	Ploidy (only for <18m & M stage)	Pre-treatment Risk Group	
L1	NA	any	any	any		Very Low	
	Amp	any	any	any		High	
L2	NA	< 18m	any	No		Low	
				Yes		Intermediate	
		≥ 18m	Any except age > 5y, undifferentiated/ poor differentiated	No		Low	
				Yes		Intermediate	
	Amp	any	any	any	any	any	High
							High
M	NA	<18m	any	any	Hyperdiploid	Low	
					Diploid	Intermediate	
	Amp	any	any	any	any	any	High
							High
MS	NA	<18m	any	No		Very Low/ Low	
	Amp	<18m	any	any		High	

NA: non amplification

# 兒癌-Neuroblastoma

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## International Neuroblastoma Risk Group Staging System (INRG)

Stage	Description
L1	Locoregional tumor without IDRFs
L2	Locoregional tumor with one or more IDRFs
M	Distant metastatic disease (except Ms)
MS	INRG Stage L1 or L2 tumor with metastatic disease confined to skin and/or liver and/or bone marrow

## Life Threatening Symptoms (LTS)

<b>Intraspinal neuroblastoma</b>
<b>Systemic upset</b>
<b>Pain requiring opiate treatment</b>
<b>Gastrointestinal</b> : Vomiting needing NG/IV support ; BW loss >10%
<b>Respiratory</b> : without evidence of infection but tachypnoea >60 ; oxygen need or ventilatory support
<b>Cardiovascular System</b> : HTN; IVC compression
<b>Renal</b> : impaired renal function; poor urine output(<2mL/kg/hour); hydroureter/hydronephrosis
<b>Hepatic</b> : abnormal liver function >2 ULN; evidence of DIC; platelets <50 x 10 <sup>9</sup> /L
<b>Bladder/Bowel dysfunction secondary to a mass effect.</b>
<b>A very large tumor volume causing concern of possible tumor rupture and/or the possible rapid development of systemic upset</b>

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## APPENDIX V. Image Defined Risk Factors (IDRF)

Anatomic region	Description
Ipsilateral tumor extension within two body compartments	Neck-chest, chest-abdomen, abdomen-pelvis
Neck	Tumor encasing carotid and/or vertebral artery and/or internal jugular vein Tumor extending to base of skull Tumor compressing the trachea
Cervico-thoracic junction	Tumor encasing brachial plexus roots Tumor encasing subclavian vessels and/or vertebral and/or carotid artery Tumor compressing the trachea
Thorax	Tumor encasing the aorta and/or major branches Tumor compressing the trachea and/or principal bronchi Lower mediastinal tumor, infiltrating the costo-vertebral junction between T9 and T12
Thoraco-abdominal	Tumor encasing the aorta and/or vena cava
Abdomen/pelvis	Tumor infiltrating the porta hepatis and/or the hepatoduodenal ligament Tumor encasing branches of the superior mesenteric artery at the mesenteric root Tumor encasing the origin of the coeliac axis, and/or of the superior mesenteric artery Tumor invading one or both renal pedicles Tumor encasing the aorta and/or vena cava Tumor encasing the iliac vessels Pelvic tumor crossing the sciatic notch
Intraspinal tumor extension whatever the location provided that:	More than one third of the spinal canal in the axial plane is invaded and/or the perimedullary leptomenigeal spaces are not visible and/or the spinal cord signal is abnormal
Infiltration of adjacent organs/ structures	Pericardium, diaphragm, kidney, liver, duodeno-pancreatic block, and mesentery
Conditions to be recorded, but <i>not</i> considered IDRFs	Multifocal primary tumors Pleural effusion, with or without malignant cells Ascites, with or without malignant cells

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## TREATMENT ASSIGNMENT: TPOG-N2020-VLR

1. If patient is stage L1, arrange total tumor excision then follow up.
2. If patient is stage MS without LTS, please keep close follow-up. Surgical resection of primary tumor is not indicated. If progression disease (PD) or life threatening symptoms (LTS) develops in follow-up, the treatment would upgrade to low risk protocol.
3. pre-survey: history, physical examinations, CBC/Diff/Plts, PT, PTT, LDH, ferritin, ALT, bil, creatinine, urinalysis, urine 12/24 hr VMA, CT/MRI of primary/metastatic sites, MIBG/PET/bone scan, BM aspirations and biopsies for stage MS , tumor biology studies for all patients.
4. Post-surgical evaluations for patients

	Mos 1	Mos 2	Mos 3	Mos 6	Mos 9	Mos 12	Mos 18&24	Yearly
Hx, PE	X	X	X	X	X	X	X	X
CBC/Diff/Plts	X	X	X	X	X	X	X	X
Urine VMA			X <sup>1</sup>	X <sup>1</sup>	X <sup>2</sup>	X <sup>2</sup>	X <sup>1</sup>	X <sup>2</sup>
CT/MRI <sup>3</sup>			X	X		X		
Echo	X	X <sup>5</sup>	X	X	X <sup>5</sup>	X	X	X
BMA/Bx <sup>4</sup>			X	X <sup>2</sup>		X <sup>2</sup>	X <sup>2</sup>	X <sup>2</sup>
MIBG/PET			X <sup>5</sup>	X <sup>2</sup>		X <sup>2</sup>	X <sup>2</sup>	X <sup>2</sup>

1. Do only if abnormal at diagnosis.
2. Do only when abnormal at latest study.
3. Use MRI if it provides more information (e.g. spinal). Use the same image modality throughout the study.
4. Do only for patients with stage MS with marrow positive at diagnosis.
5. Do only for patients with stage MS



## TREATMENT ASSIGNMENT: TPOG-N2020-LR

### Stage L2

Treat with VP/Carbo x 4 courses.

- If IDRFs become negative, consider surgery.
- If IDRFs are still positive and histopathology are Ganglioneuroblastoma-Intermixed (Schwannian stroma-rich) type at the time of presentation, consider close follow-up or debulking surgery for relief of symptoms.
- If IDRFs are still positive and histopathology are **NOT** Ganglioneuroblastoma-Intermixed type at the time of presentation, consider debulking surgery, then CADO x 2 courses.

### Stage M

Treat with VP/Carbo x 2 courses.

- if LTS is negative, treat with VP/Carbo x 2 courses.
- if LTS is positive, treat with CADO x 2 courses.

Then re-evaluate the disease status

- if IDRFs become negative and metastatic remission achieve, consider surgery, then follow up
- if IDRFs are still positive and metastatic remission achieve, consider debulking surgery, then CADO x 2 courses.
- if IDRFs are still positive and metastatic remission do not achieve, consider CADO x 4 courses. Then follow up closely.

### Stage MS with LTS

Treat with VP/Carbo x 2 courses.

- if LTS becomes negative, follow up closely.
- if LTS is still positive, treat with CADO x 2 courses.
- If LTS does not respond rapidly enough to chemotherapy, consider radiotherapy.

Note : Surgical resection of primary tumor is not indicated in this group

## TREATMENT ASSIGNMENT: TPOG-N2020-IR

### Stage L2

Treat with VP/Carbo x 2 courses then CADO x 2 courses.

Then re-evaluate the disease status:

- if IDRFs become negative, consider surgery, then VP/Carbo x 1 course + CADO x 1 course.
- If IDRFs are still positive and histopathology is NOT undifferentiated/poor differentiated type at the time of presentation, consider debulking surgery, then CADO x 2 courses.
- If IDRFs are still positive and histopathology is undifferentiated/poor differentiated type at the time of presentation, consider debulking surgery and CADO x 2 courses. Then radiotherapy and 6 courses of 13 cis-retinoid acid treatment are suggested.

### Stage M

Treat with VP/Carbo x 2 courses then CADO x 2 courses.

Then re-evaluate the disease status:

- if IDRFs become negative and metastatic remission achieve, consider surgery, then VP/Carbo x 1 course + CADO x 1 course.
- if IDRFs are still positive and metastatic remission achieve, consider debulking surgery, then CADO x 2 courses.
- if IDRFs are still positive and metastatic remission do not achieve, consider CADO x 4 courses.

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## TREATMENT ASSIGNMENT: TPOG-N2020-IR

Pre-study evaluations included history, physical examinations, CBC/Diff/Plts, PT, PTT, LDH, ferritin, ALT, bilirubin, creatinine, urinalysis, urine 12/24 hr VMA, CT/MRI of primary/metastatic sites, MIBG/PET/bone scan, BM aspirations and biopsies, tumor biology studies for all patients; and audiogram/ABER, echocardiogram for patients planned for chemotherapy.

Post-chemotherapy evaluations for TPOG-NBL2020-LR/IR

Month	PE	CBC/Diff/Plt	CT/MRI	Echo		Creat#	VMA**	Audio ABER
1	X	X		X		X		
3	X	X	X	X		X	X	
6	X	X	X	X			X	
9	X	X		X				
12	X	X	X	X			X	X
15	X	X						
18	X	X	X*	X			X	
21	X	X						
24	X	X	X*	X			X	X
30	X	X						
36	X	X	X*	X			X	
Yearly	X	X	X*	X*			X	

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## NOTE UNDER CHEMOTHERAPY

Baktar prophylaxis 150 mg/m<sup>2</sup> TMP component/day in 2 divided doses 3 times/wk on consecutive days

Chemotherapy doses are adjusted for children less than 365 days of age or who are  $\leq$  12 kg in weight, and are given in parenthesis below.

(Note) Organ function should be adequate (except those abnormal due to neuroblastoma): Serum creatinine < 1.5x normal; Bilirubin < 1.5x normal; AST/ALT < 2.5x normal; Shortening fraction of > 27% by echocardiography.

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## 化學治療處方建議表: VP/carbo (etoposide, carboplatin)

Courses of VP/Carbo are given at 21 day intervals

DAY	1	2	3
Carboplatin	X	X	X
Etoposide	X	X	X

DRUG	Dose (mg/kg)	Dose (mg/m <sup>2</sup> )
Carboplatin	6.6 mg/kg	200 mg/m <sup>2</sup> in 5% dextrose (5 ml/kg) over 1 hr daily x 3
Etoposide (VP16)	5.0 mg/kg	150 mg/m <sup>2</sup> in 0.9% saline (12.5 ml/kg) over 2 hrs daily x 3

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## 化學治療處方建議表: CADO (cyclophosphamide, doxorubicin, vincristine)

Courses of CADO are given at 21 day intervals

DAY	1	2	3	4	5	6	7	8
Cyclophosphamide	X	X	X	X	X			
Doxorubicin				X	X			
Vincristine	X							X

DRUG	Dose (mg/kg)	Dose (mg/m <sup>2</sup> )
Cyclophosphamide	10 mg/kg	300 mg/m <sup>2</sup> in 5% dextrose (5 ml/kg) over 1 hr, daily x 5 days
Doxorubicin	1 mg/kg	30 mg/m <sup>2</sup> in 0.9% saline over 6 hours on days 4 and 5
Vincristine	0.05 mg/kg	1.5 mg/m <sup>2</sup> (max 2mg) Bolus injection on days 1 and 8

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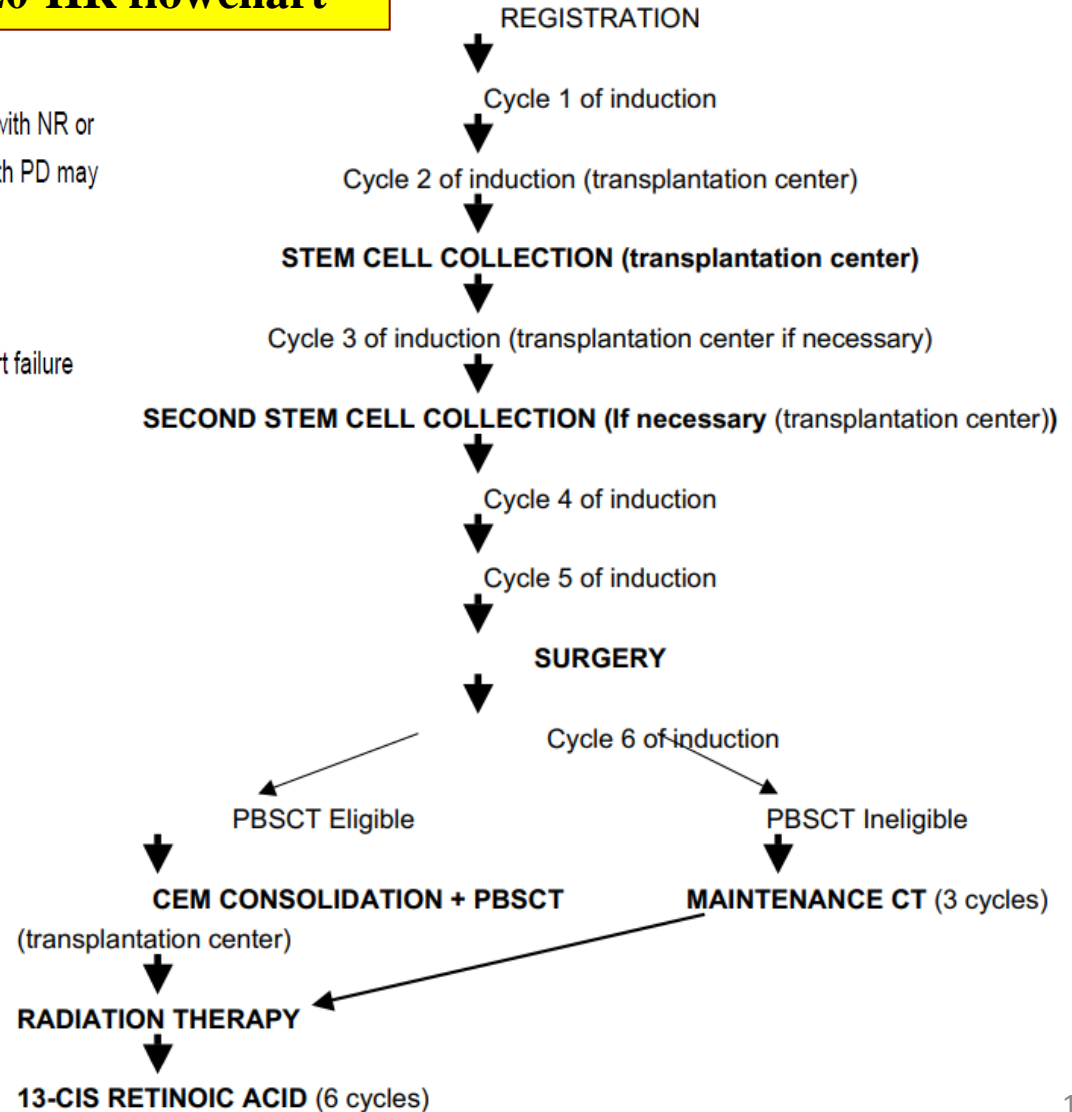
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## TREATMENT ASSIGNMENT: : N2020-HR flowchart

### Eligibility for PBSCT Consolidation

- 1 Patients with CR, VGPR, or PR are encouraged to proceed to PBSCT; patients with NR or MR may proceed to PBSCT or receive other experimental regimens; patients with PD may receive other experimental regimens.
- 2 Sufficient stem cells:  $\geq 3 \times 10^6$  CD34 cells/kg
- 3 ALT, bili < 3x normal
- 4 Shortening fraction  $\geq 28\%$ , or ejection fraction  $\geq 55\%$ , no clinical congestive heart failure
- 5 CCR  $\geq 60$  ml/min/1.73 m<sup>2</sup>
- 6 Patients with uncontrolled (culture or biopsy positive) infections are not eligible.
- 7 Patients who are pregnant or lactating are not eligible.
- 8 HIV seropositive patients are not eligible.



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化學治療處方建議表：N2020-HR (con.)

## Chemotherapy

Cycle 1, 2, 4, 6 of induction: CDV

### Day 0&1

Cyclophosphamide 2100mg/m<sup>2</sup> (70mg/kg)\* for 6 hours

Oncovin# 0.67mg/m<sup>2</sup> for 24 hours

Adrimycin 25mg/m<sup>2</sup> (0.83mg/kg)\* for 24 hours

### Day 2

Oncovin# 0.67mg/m<sup>2</sup> for 24 hours

Adrimycin 25mg/m<sup>2</sup> (0.83mg/kg)\* for 24 hours

\* For children less than 365 days of age or who are  
≤ 12kg in weight

# 0.022mg/kg if < 12kg, 0.017mg/kg if < 12 months

Cycle 3, 5 of induction: CiE

### Day 0, 1&2

Etoposide 200mg/m<sup>2</sup> (6.67mg/kg)\* for 2 hours

Cisplatin 50mg/m<sup>2</sup>(1.66mg/kg)\* for 1 hour

### Day 3

Cisplatin 50mg/m<sup>2</sup>(1.66mg/kg)\* for 1 hour

\* For children less than 365 days of age or who are  
≤ 12kg in weight



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## 化學治療處方建議表:N2020-HR (con.)

### Chemotherapy for PBSCT

		BUMEL MAT								
DRUG	DOSE	DAY	-7	-6	-5	-4	-3	-2	-1	0
Busulfan	< 9 kg: 16.0mg/kg 9 kg to < 16 kg: 19.2 mg/kg 16 kg to 23 kg: 17.6 mg/kg >23 kg to 34 kg: 15.2 mg/kg >34 kg: 12.8 mg/kg			↓	↓	↓	↓			↓ Stem cell infusion
MELPHALAN	140 mg/m <sup>2</sup> I.V. short infusion (15') not before 24h after last busulfan dose								☐↓	

#### 13-cis-Retinoic Acid therapy

Begin at day +100 after PBSCT; no RT for over 5 days

13-cis-RA 160mg/m<sup>2</sup>/day (5.33mg/kg/day)\* for BID, for 14 days, followed by 14 days rest per cycle, for 6 cycles

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## 化學治療處方建議表:N2020-HR (con.)

Table 4. Required Observations During Follow-up After Completion of 13-cis-Retinoic Acid<sup>1</sup>

Observ.	3 M	6 M	9 M	1 Y	1.5 Y	2 Y	2.5 Y	3 Y	3.5 Y	4 Y	4.5 Y	5 Y	Y	At Rel
PE <sup>1</sup> , Ht <sup>1</sup> , Wt <sup>1</sup>	X	X	X	X	X	X	X	X	X	X	X	X	X	
CBC <sup>1</sup> , DC <sup>1</sup>	X	X	X	X	X	X	X	X	X	X	X	X	X	
EKG, ECHO <sup>2</sup>				X								X		
<b>BMA &amp; Bx</b>	X			X										X
Tumor Imaging		X	X	X	X	X	X	X						X
MIBG/PET	X	X		X	X	X	X	X						X
24 hr urine VMA	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Perform Status				X		X		X		X		X		
TSH, T4, PFT <sup>3</sup>				X										

1. Perform PE and CBC, PLT, DC monthly for one year after transplant.
2. If abnormal, repeated annually. If child is < 5 yrs, an additional test should be done at 5 yrs.
3. Perform PFT (pulmonary function test) if child is  $\geq$  5 yrs. If child is < 5 yrs, delay until he is 5 yrs.

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## Chemotherapy with *abnormal renal function*( $Ccr < 100\text{ml/min}/1.73\text{m}^2$ )

**Carboplatin** using modified Calvert formula or 10mg/kg if  $\leq 12\text{kg}$

$$\text{total dose (mg/day)} = (\text{CCR} \times \text{BSA}/1.73 + 15 \times \text{BSA}) \times 4.1$$

**Etoposide** 200mg/m<sup>2</sup>(6.7mg/kg)\*4 for 24 hours

**Melphalan** 60mg/m<sup>2</sup>(2mg/kg)\* 3

\* For children less than 365 days of age or who are  $\leq 12\text{kg}$  in weight

## Maintenance therapy

### 13-cis-Retinoic Acid Therapy

- Begin at day +100 after PBSCT.
- LFT < Gr2 toxicity, normal RFT, no proteinuria, no > Gr1 hematuria, Ca/UA/TG  $\leq$  2N
- No RT for over 5 days
- Dosage: 13-cis-RA 160 mg/m<sup>2</sup>/day (5.33 mg/kg/day if  $\leq$  12 kg) for b.i.d. for 14 days, followed by 14 day rest per cycle with total of 6 cycles.
- Supportive care: topical vitamin E, avoid sun exposure
- Criteria prior to each cycle: a. ALT < 5N, b. skin toxicity < Gr1, c. serum TG < 300 mg/dL, d. No hematuria/proteinuria, e. serum creat < 1.5 mg/dL

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化學治療處方建議表:N2020-HR (con.)

## Maintenance therapy (optional)

**Dinutuximab and 13-cis-Retinoic Acid (13-cis RA) Therapy will start after completion of radiotherapy**

### Treatment Schema

#### Cycle 1-5

Day 1-5/10 Dinutuximab 100 mg/m<sup>2</sup> in 5 or 10 days continuous infusion  
in 0.9% NaCl total 100 mL

Day 1-10 GM-CSF 250 mcg/m<sup>2</sup> SC qd  
for minimum 10 days or longer until ANC > 1500/ $\mu$ L

Day 15-28 13-cis-RA 160 mg/m<sup>2</sup>/day (5.33 mg/kg/day if < 12 kg) b.i.d.  
for 14 days, followed by 14 days rest per cycle  
with total of 6 cycles.

Cycle 6  
Day 15-28 13-cis-RA 160 mg/m<sup>2</sup>/day (5.33 mg/kg/day if < 12 kg) b.i.d.  
for 14 days

	Course 1	Course 2	Course 3	Course 4	Course 5	Course 6
D 1-5/10	Dinutuximab	Dinutuximab	Dinutuximab	Dinutuximab	Dinutuximab	
D 1-10	GM-CSF	GM-CSF	GM-CSF	GM-CSF	GM-CSF	
D 15-28	13 Cis-RA	13 Cis-RA	13 Cis-RA	13 Cis-RA	13 Cis-RA	13 Cis-RA

## SURGERY GUIDES

1. The goal of surgery is to provide diagnostic material at diagnosis (biopsy), to accurately stage disease through sampling of non-adherent lymph nodes, and to attempt maximal safe resection either at diagnosis or after chemotherapy (second-look procedure).
2. Tumors suitable for resection at presentation:
  - L1 by INRG definition (localized tumor: IDRF negative)Tumors suitable for biopsy only at presentation:
  - L2 by INRG definition (localized tumor: IDRF positive)
  - M and MS tumors by INRG definition (metastatic disease)\*

\*Excision of the primary tumor may be an alternative diagnostic procedure to biopsy in metastatic tumors, provided the primary tumor is IDRF negative.
3. If a tumor remains IDRF positive after chemotherapy this is not an absolute contraindication to surgery. Resection may still be recommended if evaluation of the primary tumor suggests that the risk to life, or of major functional loss, is less than the risk from leaving residual disease.

### 7.1 Indications

- Symptomatic low risk patients with stage MS that have not responded rapidly enough to chemotherapy.
- Intermediate risk patients with unfavorable biology (undifferentiated/poor differentiated type ) who achieved a PR after treatment.  
(Note) Free of ileus, ANC > 1,000/ $\mu$ L, Hemoglobin > 10 g/dL before RT
- All High risk at >28 days post-HSCT and fulfill the following: (1) ANC > 1,000/ $\mu$ l; (2) No requirement for PLT transfusion; (3) Mucositis nearly resolved; (4) ALT < 80 U/L, Bil < 1.5 mg/dl, No VOD (if liver in the field); (5) No respiratory distress on room air (if lung or trachea in the field); (6) Alb > 3 g/dl without albumin infusion for 1 week (if abdominal irradiation); (7) Cre < 1.5 mg/dl (if kidney in the field); (8) No hematuria (if kidney or bladder in the field)

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## RADIOTHERAPY GUIDES -2

### 2. Dosage :

- ◆ For low risk children with stage 4S disease, 150 cGy x 3 fractions for the liver
- ◆ For intermediate risk children with unfavorable biology (undifferentiated/poor differentiated type ) who achieved IDRF positive after treatment, 2,160 cGy (e.g. 180 cGy x 12 fractions) over primary site
- ◆ For high risk children, 2,160 cGy (e.g. 180 cGy x 12 fractions) over primary site and metastatic sites.

### 3. Critical Organs :

- ◆ Peritoneal cavity: < 1,500 cGy for contralateral kidney.
- ◆ Thorax: < 1,500 cGy for 2/3 or more of the lung volume.
- ◆ Liver: < 1,500 cGy for 2/3 or more of the liver volume.

### 4. Extent:

2 cm margin in all directions around the residual tumor (pre-operative volume if surgery before RT)



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## RESPONSE ASSESSMENT

- (1) To measure treatment response, International Neuroblastoma Response criteria will be used as in [APPENDIX III](#). Measurable tumor is defined as the products of the largest x widest perpendicular diameters. Elevated urine catecholamine levels and quantitative tumor cell invasion of bone marrow are also considered measures of tumor.
- (2) Content and time schedule of evaluation for each treatment assignment is listed in each protocol.

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癌症藥物停藥準則

影像學檢查，若腫瘤反應為NR或PD (定義請見[APPENDIX III](#)「反應標準」)，應停止或改變治療方式。

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## APPENDIX III. International Neuroblastoma Response Criteria

Response	Primary tumor	Metastatic Sites
<b>CR</b>	No tumor	No tumor; catecholamines normal
<b>VGPR</b>	Decreased by 90-99%	No tumor; Residual <sup>99</sup> Tc bone changes allowed
<b>PR</b>	Decreased by > 50%	All measurable sites decreased by > 50% <u>Bones and bone marrow</u> : Number of positive sites decreased by > 50%; no more than 1 positive bone marrow site allowed in biopsy.
<b>MR</b>	No new lesions; > 50% reduction of any measurable lesion (primary or metastases) with < 50% reduction in any other; < 25% increase in any existing lesion.	
<b>NR</b>	No new lesions; < 50% reduction but < 25% increase in any existing lesion.	
<b>PD</b>	Any new lesion; increase of any measurable lesion by > 25% ; previous negative marrow positive for tumour.	

**CR** : Complete Response ; **VGPR** : Very Good Partial Response ; **PR** : Partial Response;  
**MR** : Mixed Response ; **NR** : No Response ; **PD** : Progressive Disease